PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

N. Sandor Racz et al.

Serial No.: 10/694,235

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For: SAFETY SPINAL NEEDLE

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Examiner: Nicholas D. Lucchesi

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APPEAL BRIEF

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sirs:

This brief is submitted in the format required under 37 C.F.R. § 41.37(c). The Office is hereby authorized to charge Deposit Account 201469 in the amount of $540.00 for the fee under 37 C.F.R. § 41.20(b)(2) for filing a brief in support of an appeal.

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I). REAL PARTY IN INTEREST

The inventors assigned their interest in the application to Epimed International, Inc. in an assignment that was recorded with the United States Patent Office on 27 October 2003, at Reel 014644, Frame 0100. Subsequently, Epimed International, Inc. assigned its interest in the application to Custom Medical Applications, Inc. This assignment was recorded with the United States Patent and Trademark Office on 11 January 2010 at Reel 023770, Frame 0032. Custom Medical Applications, Inc. is the present owner of the application and is therefore, the real party in interest.

II) RELATED APPEALS AND INTERFERENCES

The Appellant inventors, the Appellant's representative, and the Assignee are not aware of any pending appeal or interference that would relate to, directly affect, be directly affected by, or have a bearing on the Board's decision in the pending appeal.

III.) STATUS OF THE CLAIMS

Claims 1-24 and 26-34 are pending in the application.

Claims 7, 10, 11, 13, 19, 22 and 26 have been withdrawn from consideration

Claims 1-6, 8, 9, 12, 14-18, 20, 21, 23, 24, and 27-34 stand rejected.

No claims are allowed.

Claims 1-6, 8, 9, 12, 14-18, 20, 21, 23, 24, and 27-34 are the subject of the pending appeal.

IV.) STATUS OF AMENDMENTS

An Amendment was filed on 24 August 2009 responsive to the final rejection of the application. The amendments set forth in the Amendment of 24 August 2009 were entered in the application as indicated in the Advisory Action dated 3 September 2009. No amendments have been proposed in the present application subsequent to the Amendment filed 24 August 2009.

V.) SUMMARY OF THE CLAIMED SUBJECT MATTER

Independent claim 1 of the presently claimed invention is directed to a flexible spinal needle catheter assembly. With reference to FIG. 1 of the presently considered application, the claimed assembly as set forth in claim 1 includes a flexible needle catheter which defines a hollow bore for conveying a medicating agent. The flexible needle catheter has a proximal end which defines a leading edge.

A support needle is releaseably secured to the flexible needle catheter. The support needle is positioned within the hollow bore. The support needle has a first end which defines a pencil point, non-cutting piercing point which is configured to penetrate the dura mater of a patient. The piercing point is has an outside diameter configured such that after the insertion of the needle assembly through the dura mater and a subsequent withdrawal of the flexible needle catheter assembly from the dura mater of a spine of a patient, a puncture opening produced by the insertion of the needle assembly is of dimensions which permit the dura mater to substantially reseal the puncture opening formerly occupied by the flexible needle assembly within the dura mater.

The support needle defines a hollow lumen which extends along a length of the support needle. The support needle further defines an opening proximate the end of the support needle which communicates with the environment. The support needle is dimensioned such that the end of the support needle is positioned outside of the bore of the flexible needle catheter. The non-cutting pencil point tip and the opening are both positioned outside of the bore of the flexible needle assembly.

A solid stylet is releasably secured within the lumen of the support needle. In a first condition,

the stylet is positioned to preclude access from the environment to the lumen through the opening. *As-filed Application* at ¶ [0031] through ¶ [0036].

Independent claim 16 of the presently claimed invention is directed to a flexible needle assembly for inserting a distal end of a flexible spinal needle through the dura mater of a patient's spine. The needle assembly includes a flexible needle, a support needle having a proximal end and a distal end. A pencil point, noncutting piercing point is defined on the distal end. The support needle is releaseably secured to the flexible needle to resist relative motion between the distal end of the flexible needle and the non-cutting piercing point during an insertion of the flexible spinal needle assembly into a patient. The flexible needle is cried exterior to the support needle to thereby expose the piercing point when the assembly is positioned for insertion into the patient. FIG. 1 illustrates the various component elements of the claimed structure. The nature and operation of the claimed structure is set forth at ¶ [0031] through [0036].

Independent claim 25 of the presently claimed invention is directed to a flexible spinal needle which includes a support needle, having a pencil point, non-cutting piercing tip; a flexible needle body, having an elongated hollow tube; and a kink sleeve disposed on a portion of the flexible needle body. The kink sleeve is configured to prevent a linking of the flexible needle body when the flexible needle body is bent beyond its flexible structural resilience. The flexible needle boy is configured to be slidably mounted on an exterior of the support needle. With reference to FIGS. 1 through 3 and 5 and ¶ [0031] through ¶ [0036].of the presently considered application, the needle recited in claim 25 includes a structure which is adapted to permit an insertion into the dura mater of a patient without an unacceptable level bending of the support

needle.

Independent claim 27 of the presently claimed invention is directed to a flexible spinal needle assembly having a support needle having a first end which defines a pencil point, non-cutting piercing point and a hollow bore with an opening positioned proximate the first end for allowing access to the bore. A flexible needle is slidably mounted on the exterior of the support needle such that the first end of the support needle protrudes from the flexible needle exposing the piercing point and the opening. The flexible needle is fabricated to have a sufficient transverse flexibility to accommodate a patient's torso bending movement so as to substantially reduce the patient's awareness of the presence of the flexible needle. FIG. 1 illustrates the various component elements of the claimed structure. The nature and operation of the claimed structure is set forth at ¶ [0031] through ¶ [0036].

VI.) GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

(A) Whether Claims 1-4, 6, 8, 9, 12, 14-18, 20 23, 25, 27-29 and 32-34 are unpatentable under 35 U.S.C. § 102 over Zohmann (USPGPub 2002/0099335 A1)?

(B) Whether Claims 5 and 21 are unpatentable under 35 U.S.C. § 103(a) over Zohmann (USPGPub 2002/0099335 A1) in view of Kreuzer et al. (U.S. Patent No.5,116,323)?

(C) Whether Claims 28, 29 and 34 are unpatentable under 35 U.S.C. § 103(a) over Zohmann (USPGPub 2002/0099335 A1) in view of Smith et al. (U.S. Patent No.5,250,035)?.

(D) Whether Claims 30 and 31 are unpatentable under 35 U.S.C. §103(a) over Zohmann (USPGPub 2002/0099335 A1) in view of Gibbons et al. (USPGPub 2005/0070881 A1)?

(E) Whether Claim 15, was appropriately objected to under 37 CFR § 1.75(c)?

(F) Whether Claims 18 and 30 were appropriately objected to in view of perceived informalities?

VII.) ARGUMENT

(A) Authorities Relied Upon

Under 35 U.S.C. §102(a) a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Brothers v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Unless a single prior art reference describes "all of the limitations claimed" **and** "all of the limitations [are] **arranged or combined in the same way** as recited in the claim, it cannot be said to prove prior invention of the thing claimed and, thus, cannot anticipate under 35 U.S.C. § 102." *Net MoneyIN Inc. v. VeriSign Inc.*, 545 F.3d 1359, 1371 (Fed. Cir. 2008) (emphasis added). A single prior art reference must "clearly and unequivocally" describe the claimed invention "without *any* need for picking, choosing, and combining various disclosures not directly related to each other by the teachings of the cited reference." *Id.* (*Citing In re Arkley*, 455 F.2d 586, 587 (C.C.P.A. 1972)).

Under 35 U.S.C. §103(a), "[a] patent may not be obtained though the invention is not identically disclosed or described as set forth in [35 U.S.C. §102], if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." To establish a *prima facie* case of obviousness, the Examiner must clearly and expressly articulate the reasons why the claimed invention would have been obvious in view of the prior art reference or references. *KSR Int'l Co. v. Teleflex Inc.*,

127 S. Ct. 1727, 1740-41, 167 L.Ed.2d 705, 75 USLW 4289, 82 U.S.P.Q.2d 1385 (2007). Moreover, the prior art reference (or references when combined) must teach or suggest all the claim limitations. *In re Royka*, 490 F.2d 981, 985 (C.C.P.A. 1974); M.P.E.P. § 2143.03.

Where the Examiner asserts that it would have been obvious to combine teachings from two or more references to obtain the claimed invention, the Examiner must determine whether there is "an apparent reason to combine the known elements in the fashion claimed by the patent at issue." *KSR Int'l Co.*, 127 S. Ct. at 1740-41. Rejections on obviousness grounds "cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *Id.* at 1741 (*quoting In re Kahn*, 441, F.3d 977, 988 (Fed. Cir. 2006)). Further, "[i]f a proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." M.P.E.P. § 2143.01; *In re Gordon*, 733 F.2d 900, 902; 221 U.S.P.Q. 1125 (Fed. Cir. 1984).

Finally, to establish a *prima facie* case of obviousness there must be a reasonable expectation of success. *In re Merck & Co., Inc.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986). Furthermore, the reason that would have prompted the combination and the reasonable expectation of success must be found in the prior art, common knowledge, or the nature of the problem itself, and not based on the Applicant's disclosure. *DyStar Textilfarben GmbH & Co. Deutschland KG v. C. H. Patrick Co.*, 464 F.3d 1356, 1367 (Fed. Cir. 2006); M.P.E.P. §§ 2143-44. Underlying the obvious determination is the fact that statutorily prohibited hindsight cannot be used. *KSR*, 127 S. Ct. at 1742; *DyStar*, 464 F.3d at 1367.

(B) Summary of Cited Prior Art

The Examiner has relied on USPGPub 2002/0099335 A1 (Zohmann); U.S. Patent No.5,116,323, (Kreuzer et al.); U.S. Patent No.5,250,035, (Smith et al.) and USPGPub 2005/0070881 (Gibbons et al.) in rejecting the pending claims. The disclosures of these references are summarized below.

Zohmann is directed to a needle for facilitating lumbar puncture procedures. More specifically, Zohmann relates to an atraumatic needle for use in reducing loss cerebral spinal fluid. The Zohmann apparatus includes a hollow introducer component, which is a few centimeters in length. The introducer has a sharp end which is used to puncture the skin. A hollow needle, having a rounded, blunt end, is slidably disposed within the hollow introducer. The needle has a hub with raised side port indicators and a magnifying window for viewing the return of fluid in the hub. A stylet is slideably disposed within the hollow needle to selectively occlude the needle and control the flow of fluid therein. See col, 4, lines 21 through 39 and col. 6, lines 44 through 47. Also see FIGS 1-8.

Kreuzer et al (hereinafter "Kreuzer") is directed to an assembly for use in easing the insertion and placement of an arterial catheter in the blood vessel of a patient. The assembly includes an insertion needle and a guide tube. The guide tube passes through a lumen of the catheter to extend outwardly from the catheter. The insertion needle is disposed within the hollow interior of the guide tube to extend out of the end of the guide tube. The needle defines a sharp end which is designed for insertion through the skin and into the blood vessel of the patient. Reference is made to col. 2, lines 66-68 and col. 3, lines 1-14. Further reference is made to FIGS. 1-4.

Smith et al (hereinafter "Smith") relates to a needle system which includes a plastic cannula and a stylet. The cannula has a non-pointed, but beveled distal end and a clear plastic hub on its proximal end. The stylet is adapted to be inserted into the bore of the cannula. The stylet has a dura- piercing tip on its distal end which projects beyond the nonpointed end of the cannula when the stylet is inserted into the cannula. Once the assembly of the cannula and stylet is inserted sufficiently into the patient to position the end of the cannula in that portion of the patient to which a medicament is to be administered, the stylet is withdrawn from the assembly to facilitate the insertion of a catheter into the cannula such that the end of the catheter is positioned proximate the end of the cannula. Reference is made to FIGS. 10 and 12-14.

Gribbons et al. (hereinafter "Gribbons") is directed to a catheter which defines a guide wire lumen and an inflation lumen. Gibbons teaches a metal ribbon 714 which is positioned to provide support within the body of the catheter. See FIG. 7.

(C) Objection to Claim 15:

Claim 15 has been objected to under 37 CFR 1.75c as being in an improperly dependent form for failing to further limit the subject matter of a previous claim. In their Amendment of 24 August 2009, appellants amended the language of Claim 15. This amendment was entered by the Office in the Advisory Action dated 3 September 2009. In Appellants' amendment, Claim 15 was amended to clearly specify that the stylet was slidably mounted in the support needle. The Examiner has contended that the subject matter of claim 15 was amended into independent claim 1 and therefore claim 15 fails to further limit the subject matter of a previous claim. Appellants respectfully submit that the subject matter of claim 15 has not been amended into claim 1. Claim 1 provides for a stylet which is releaseably secured within a lumen defined within the support

needle. Claim 1 does not indicate that the stylet is slidably mounted in the support needle. It follows that imposition of the further limitation that the stylet be slidably mounted within the lumen operates to further limit the placement of the stylet in the lumen over the limitations currently found in claim 1. In view of this consideration, appellants respectfully submit that claim 15 presently adds an additional limitation to the structure of claim 1 and therefore claim 15 is in proper dependent form responsive to 37 CFR § 1.75(c)

(D) Objection to Claim 18:

Claim 18 has been objected to in view of the recitation of the limitation "said first structure." More specifically, the Examiner maintains that this limitation lacks antecedent basis. Appellants submit that the basis of this objection has been rectified in the amendment filed on 24 September 2009, entered on in the Advisory Action mailed 3 September 2009. Specifically, the aforesaid amendment inserted the term "attach" before the word "structure" thereby conforming the referenced limitation to the structural element "first attach structure" introduced at line 2 of claim 18. In view of this amendment, appellants respectfully submit that the amendment obviates the basis of the Examiner's objection by properly establishing antecedent basis.

E) Objection to Claim 30:

Claim 30 has been objected to in view of the presence of two periods at the end of the claim. The Claim has further been objected to in view of the phrase "said flexible needle" which the Examiner asserts lacks antecedent basis. Applicant has rectified the basis of the two period objections by amendment. Further, the term catheter has been inserted into the claim after the word needle to rectify the basis of the antecedent basis objection. In preparing this brief,

appellants noted that the term "catheter" was not underlined in the set of amended claims submitted for the Examiner's consideration consistent with Office practice, nor was the second period indicated, although in both instances the text of the claim is otherwise correct. The Board is respectfully requested to treat the amendments to Claim 30 as being made in proper format for purposes of this appeal.

(F) Rejection under 35 U.S.C. § 102(b) Based on Zohmann

Appellants assert that the Examiner's novelty rejection of claims 1, 4, 6, 8, 9, 12, 14-18, 20, 23, 25, 27-29 and 32-34 under 35 U.S.C. § 102(b) is improper because the Examiner has failed to establish a *prima facie* case of lack of novelty.

The Examiner has asserted at Page 3 of the Final Office Action mailed 24 March 2009 (hereinafter "Final Office Action") that Zohmann teaches a flexible needle catheter defining a hollow bore for conveying medicating agent there through ¶[0057]. The Examiner further argued that although the introducer of Zohmann is not used in fluid delivery, it is capable of that function and also that the introducer houses a needle through which fluid is delivered. The Examiner further maintained that the Zohmann flexible needle catheter has a proximal leading edge and a support needle, disposed within a hollow bore of the flexible needle catheter and releaseably secured to the flexible needle catheter, the support needle having a first end having a pencil-point tip. The Examiner contends that a pencil-point in and of itself is not necessarily sharpened and therefore encompasses blunted tapered tips. The Examiner further argues that Zohmann discloses that the support needle defines a hollow lumen and an opening defined

proximate the first end which communicates the environment with the lumen. The Examiner maintains that first end of the support needle and the opening are positioned outside of the bore. The Examiner further argues that Zohmann teaches a solid stylet, releaseably secured within the lumen in a first condition and that a leading edge of the flexible needle catheter is proximate the tip of the support needle, that the flexible needle catheter provides feedback to the indicate dural puncture, that the support needle has a support hub with a first attach structure and a detach structure. Finally, the Examiner maintains that Zohmann teaches a hub capable of being secured to the patient as well as a kink sleeve disposed about a portion of the flexible needle.

With reference to claim 25, the Examiner argues that Zohmann teaches a flexible needle comprising a support needle having a pencil point tip, a flexible needle body having an elongated hollow tube configured to be slidably mounted on an exterior of the support needle and a kink sleeve disposed on a portion of the flexible needle body.

Appellants assert that the Examiner has failed to show that the Zohmann reference teaches all of the structural limitations set forth in each of applicant's claims.

i) Rejection of Claim 1

Applicant's Claim 1 provides a flexible spinal needle assembly which is adapted for inserting a catheter into a patient. The assembly includes three principal components, namely a catheter 15, a hollow support needle 19 and a central stylet 17. The stylet 17 is releaseably positioned within a lumen defined within the hollow support needle 19. The stylet 17 is dimensioned to close an opening 28 defined within the sidewall of the hollow support needle 19, thereby precluding the entry of material into the lumen defined within the support needle 19. The hollow support needle 19 defines a pencil point, non-cutting tip 27 which is configured for

penetrating the patient while not cutting the tissue of the patient. Specifically, the pencil point tip is configured to produce an opening in the patient of sufficient dimensions to permit the needle assembly to be inserted and positioned partially within the patient while also limiting the dimensions of that opening such that upon removal of the assembly from the patient the dura mater of the patient may readily reseal the opening in the patient. The hollow support needle 19 is disposed within a hollow bore defined within the catheter 15. In essence the catheter is slidably positioned on the exterior of the support needle. Given the positioning of the catheter 15 on the exterior of the support needle 19 and the configuration of the catheter, the instant assembly provides a structure adapted for more efficiently installing catheters having larger diameters than prior catheter installation structures.

Zohmann discloses an assembly which includes a stylet 30 which is disposed within a needle component 4. The needle component 4 defines a rounded tip 54 and an opening 53, which is configured for providing access to the hollow interior of the needle component. The needle component 4 is disposed within a hollow bore defined within an introducer 6. The introducer 6 has a leading edge which is configured for puncturing the patient and thereby defining an entry opening through which the body of the assembly may be subsequently inserted into the patient. In the Zohmann device, the drug which is to be introduced into the patient is directed through the hollow needle 4 after the stylet 2 has been withdrawn from the interior of the needle 4.

As previously noted, the instant claim1 requires a hollow needle having a pencil point, non-cutting tip which is adapted for penetrating the patient and thereby forming an entry opening for the insertion of the assembly into the patient. The pencil point tip is specifically

configured so that in use the tip will produce a dimensioned opening within the patient such that upon a removal of the assembly from the patient, the dura mater may readily reseal the opening. The configuration of "pencil point" tips is known in the art as is indicated at paragraph [0024] of the Zohmann disclosure, where Zohmann includes a rather extensive description of such tips. See also col. 4, lines 25-30 of the Smith et al reference. A pencil point tip is recognized in the art as having a specific structural configuration, see paragraph [0024] of the Zohmann specification. Specifically, a pencil point is described as a structure having a conical apex.

Appellants respectfully submit that the Zohmann reference neither discloses nor suggests such a support needle pencil point tip construction. In fact, appellants respectfully submit that Zohmann teaches away from, if not against, the use of such a tip.

Zohmann defines a needle 4 which has a rounded tip. See Col. 6, lines 45- 47. Zohmann appears to contain no disclosure of a needle 4 in his assembly having a tip which defines a conical apex, i.e. a "pencil point" tip. Nor does Zohmann teach a tip construction for a support needle which is adapted for use in penetrating a patient's skin by producing an opening in the patient's skin having dimensions such that upon a removal of the assembly from the patient the dura mater may readily reseal the opening.

In contrast to the applicant's claimed pencil point structure, Zohmann specifically criticizes the use of pencil point tips for catheter assemblies. At paragraph [0026] Zohmann indicates that such pencil point tips have specific disadvantages, Zohmann indicates that pencil point tips have a relatively abrupt shoulder at the juncture between the sloped sides of the conical tip and the cylindrical side walls of the body of the needle. Zohmann postulates that this relative abrupt change in the profile of the needle excessively distorts the dura and thereby contributes to

the presence of a post puncture hole in the dura. Zohmann believes that the use of a blunt tip on the needle 50 can rectify the problem created by the use of pencil point tips, namely the leakage of cerebrospinal fluid (CSF). Zohmann believes that such leakage can result from the use of pencil point tips.

Notwithstanding the disclosure of Zohmann and its criticism of pencil point tips, the Examiner has argued that appellants' recitation of a pencil point tip for its support needle is anticipated by the blunt, rounded tip 54 of the Zohmann needle support 4. The Examiner has argued that "a pencil-point in and of itself is not necessarily sharpened, and therefore pencil-point also encompasses blunted tapered tips, such as that shown in Zohmann." (See page 4, lines 2-4 of the Final Office Action). Applicant respectfully submits that it is impermissible for the Examiner to (1) redefine a term in the art in contradiction to the definition found in the art; (2) disregard the teachings of Zohmann which specifically teach away from the use of pencil point tips, and (3) thereafter reinterpret Zohmann as teaching the use of a pencil point tip configuration which Zohmann has explicitly and specifically rejected in his specification.

Applicant respectfully maintains that the appearance of the tip 54 of the Zohmann needle support 4 does not constitute a pencil point tip. The Examiner has provided no supporting evidence for his definition of "pencil point" as including non sharpened, blunted tapered tips. Instead, he merely posits such a definition in contradiction to evidence from the art, i.e. paragraph [0024] of Zohmann, which defines pencil pointed tips as having a conical apex. The terminology "conical apex" clearly implies a sharpened tip and not a blunt tip. Not only does the art itself support a definition of pencil point tips as including a conical apex but furthermore, the definition of "pencil point," which requires a conical apex comes from the very reference upon

which the Examiner is relying for his rejection of appellants' claims, namely Zohmann. Applicant respectfully submits that Zohmann's specific requirement that tip 54 of needle support 4 be rounded does not constitute a teaching of a structure having a conical apex, since an apex requires a surface which defines a point, not a rounded surface. Furthermore, a rounded surface, by definition, does not define a point. .It follows that the rounded tip of the Zohmann assembly does not define a conical apex and therefore it does not constitute a "pencil point" in appearance.

Applicant respectfully submits that not only does the rounded blunt tip 54 of the Zohmann assembly not define a conical apex, but furthermore, a careful reading of the Zohmann disclosure clearly demonstrates that Zohmann was aware of pencil point tips at the time he made his invention and that he specifically rejected the use of pencil point tips for use in catheter assemblies in favor of a rounded tip, See paragraph [0026] for a discussion of the disadvantages of pencil point tips.

Not only is the Examiner's position undermined by reference to the text of Zohmann, but further, the very operation of the Zohmann device argues against the Examiner's position.

In the Zohmann device an introducer 6, having a sharp edge, is used to penetrate the skin of the patient. As further disclosed at column 8, lines 15-20, Zohmann's "sharp, hollow introducer [70] component, being a few centimeters in length, is used to puncture the [patient's] skin, Given the function of the introducer, one can understand why the tip 54 of the needle support 4 is rounded. The tip 54 of the needle support 4 is not used in the Zohmann device to puncture the patient's skin. It follows that the tip 54 does not need to be configured for puncturing the skin of the patient since this function is achieved by the introducer 6.

The function of the Zohmann device differs significantly from that of the instant claims in

this regard in that applicant's device does not have an introducer. Instead, applicant's support needle 19 itself is configured to puncture the patient's skin. The catheter 15 is carried along by the support needle 19 through the puncture opening created by the tip 27 of the support needle. It follows that in the Zohmann device, the outer component, namely introducer 6, is configured to puncture the patient's skin while the second component 4, being slidably housed within the outer component introducer 6, is then driven through the outer component 4 and then through the puncture created by the outer component 6. See col. 8, lines 45-59 of the Zohmann reference.

In the instantly claimed device, the second component 19 is housed within the outer component 15 and extends outwardly from that outer component 15. The second component 19 punctures the patient by means of the pencil tip and then carries the outer component 15 through the puncture opening. Once the outer component 15 is in position, the second component can be withdrawn and the desired medicament can be administered to the patient through the outer component 15.

In the Zohmann construction the introducer 6 and the catheter needle 4 must both stay in place within the patient while the anesthesia is administered through the second catheter component 4. In contrast, in the instantly claimed device, the stylet 17 and the support needle 19 are both removed once the flexible needle 15 has been installed. Applicant submits that the operation of the two devices is quite different from one another. These differences in operation between the two devices dictate that the structural component elements to effect those operations are also quite distinctive from one another, including the pencil point tip of the support needle 19. In view of these considerations, applicant respectfully submits that the rejection of Claim 1 under 35 U.S.C. § 102(b) should now be withdrawn.

Applicant's Claim 1 requires a flexible needle catheter which defines a hollow bore configured for the passage of fluid, e.g. anesthesia there through. This flexible needle forms the catheter element of applicant's assembly. As noted above, this flexible needle is the outermost component of the three components which constitute the assembly. Given the outermost positioning of this component, this component has the largest exterior diameter, as well as largest interior diameter of any of the three components which form the assembly. As set forth in applicant's specification at paragraph [0011] a principal objective of applicant's invention is the efficient installation of catheters having larger diameters than the catheters of prior devices. While applicant's claimed device clearly achieves this objective by adopting the structure set forth in Claim 1, Applicant respectfully submits that the Zohmann device does not define a structure which achieves this objective.

In Zohmann the anesthesia is delivered to the patient through the lumen defined within the support needle 4. See Col. 7, lines 24-26. It follows that Zohmann defines a structure wherein the anesthesia carrying element is the second component of the assembly, as opposed to the claimed construction which places the anesthesia carrying component as the third or outermost component. By placing the anesthesia carrying component between the stylet 2 and the introducer 6, Zohmann's device structurally limits the diameter of the anesthesia carrying element. Instead of maximizing the diameter of the catheter, Zohmann limits the diameter of the catheter (needle 4) by requiring that the catheter 4 have a smaller diameter than the introducer 6, i.e. in the Zohmann device, the needle 4 is positioned within the bore of introducer 6 and therefore the introducer 6 must have a larger diameter than the diameter of needle 4. By adopting this particular arrangement of the components Zohmann does not address the objective of

applicant's claimed structure, namely, providing an assembly which facilitates the installation of larger diameter catheters than previously contemplated while simultaneously utilizing a penetrating device (pencil point tip) which is dimensioned to produce an opening in the patient's skin which is dimensioned to readily reseal upon a removal of the flexible needle assembly from the patient.

As noted in applicant's specification, health related concerns dictate that the size of a puncture opening to be formed in a patient during installation of a catheter must be constrained. It follows that for a given sized opening to be formed within a patient for insertion of a catheter assembly, applicant's assembly will be able to install a larger diameter catheter than would be possible using the Zohmann device. In applicant's construction, the exterior diameter of the catheter element will be substantially equivalent to the diameter of the puncture formed in the patient. In the Zohmann construction the exterior diameter of the introducer will substantially correspond to that of the puncture opening. It follows that owing to the nature of the Zohmann device, the actual diameter of the catheter must be smaller than that of the puncture opening since the catheter portion of the Zohmann device is housed within the introducer and must therefore have a smaller diameter. Given the health related necessity of limiting the size of the opening to be defined within the patient for purposes of installing the catheter, applicant's claimed structure provides a means of installing larger diameter catheters in the patient and thereby facilitates the supply of larger quantities of anesthesia than would be possible using the Zohmann device.

In view of the above referenced considerations, applicant maintains that the instant Claim 1, and the Claims dependent thereon, either directly or indirectly, namely claims 2-4, 6, 8, 9, 12, 14-18, 29 and 32-34 distinguish over the Zohmann reference and are therefore allowable

under 35 USC §102.

ii. Rejection of Claims 2 and 33

Claim 2 requires the leading edge of the flexible needle catheter to be positioned proximate the pencil point tip. Claim 2 has been rejected in view of the Examiner's determination that Zohmann teaches that the leading edge 74 of the flexible needle catheter 6 of Zohmann is positioned proximate and adjacent to the tip 54 of the support needle 4. The Examiner has directed the applicant's attention to FIG. 1 as supporting the Examiner's conclusion. A reference to FIG. 1 of Zohmann demonstrates that the leading edge 74 of the catheter 6 is not positioned proximate nor adjacent to the tip 54 of the support needle 4. Instead, the leading edge 74 is positioned proximate the center or midpoint of the flexible needle 4. Applicants respectfully submit that no conceivable construction of the Zohmann reference would place the leading edge 74 adjacent to the tip 74. In view of this consideration, applicants respectfully submit that Claim distinguishes over the Zohmann reference under the provisions of 35 USC §102.

iii. Rejection of Claims 12 and 14:

Claim 12 requires a force absorbing structure for preventing kinking of the flexible needle when the flexible needle is overly flexed. Claim 14 requires that this force absorbing structure be a kink sleeve disposed on a portion of the flexible needle. This particular feature is identified by reference number 18 in applicant's drawings. This kink sleeve functions as a force absorbing structure to prevent kinking of the flexible needle when the flexible needle is overly flexed. The Examiner has rejected Claims 12 and 14 in view of the hub nose 45 in the Zohmann disclosure. A close reading of the paragraph cited by the Examiner, namely paragraph [0016] reveals that

hub nose 45 is provided to permit a pressure fit of the needle component 4 with the proximate opening 62 of the introducer 6. Zohmann appears to give no indication that hub nose 45 functions to absorb any force nor that it operates as a kink sleeve. Applicants respectfully submit that the instant rejection is a mere hindsight reconstruction of Zohmann utilizing applicants' disclosure as a guide. In this consideration, applicants respectfully submit that Claims 12 and 14 distinguish over the Zohmann reference under 35 USC § 102.

iii. Rejection of Claims 16-18, and 20:

Claims 16-18, 20 and 23 all require a support needle which defines a pencil point tip. Regarding claims 16-18, 20 and 23 the Examiner maintains that Zohmann teaches a flexible spinal needle assembly comprising; a flexible needle, a support needle, having a proximal end and a "pencil-point" tip at the distal end. As noted above, Zohmann not only does not teach a support needle having a pencil point tip, but furthermore, Zohmann actually teaches away from the use of pencil point tips on support needles as a means of penetrating a patient. In view of these considerations, appellants submit that Zohmann fails to teach all of the limitations of Claims 16-18, 20 and 23 and therefore a rejection of these claims under 35 USC§102 is impermissible.

iv The Rejection of Claim 23 and 25:

Claims 23 and 25 both require a flexible needle which includes a kink sleeve disposed on a portion there to prevent kinking of the flexible needle when the flexible needle is extended beyond the substantial flexure point. Applicants respectfully submit that the Zohmann reference fails to teach such a kink sleeve. As noted above this kink sleeve functions as a force absorbing structure to prevent kinking of the flexible needle when the flexible needle is overly flexed. The

Examiner has rejected Claims 23 and 25 in view of the hub nose 45 in the Zohmann disclosure. A close reading of the paragraph cited by the Examiner, namely paragraph [0016] reveals that hub nose 45 is provided to permit a pressure fit of the needle component 4 with the proximate opening 62 of the introducer 6. Zohmann appears to give no indication that hub nose 45 functions to absorb any force nor that it operates as a kink sleeve. Applicants respectfully submit that the instant rejection is a mere hindsight reconstruction of Zohmann utilizing applicants' disclosure as a guide. In this consideration, applicants respectfully submit that Claims 12 and 14 distinguish over the Zohmann reference under 35 USC § 102.

v: The Rejection of Claim 27:

.Claim 27 requires a flexible needle having a pencil point, non-cutting piercing point. Referring to claim 27, the Examiner submits that Zohmann teaches a flexible needle assembly comprising a support needle having a pencil point tip and a hollow bore and a flexible needle slidably mounted on an exterior portion of the support needle such that the first of the support needle protrudes from the flexible needle. As previously noted, Zohmann does not teach a support needle having a pencil point tip. In view of the requirement of claim 27 of such a pencil point tip, and in the absence of a teaching in the Zohmann reference of such a pencil point tip, appellants respectfully submit that a rejection of claim 27 under 35 USC §102 over Zohmann is impermissible.

(E) Rejection of Claims 5, 21, 28, 29 30, 31, and 34 under 35 U.S.C. § 103(a) Based on Zohmann in Combination with Various Cited References:

Appellants assert that the Examiner's obviousness rejection of claims 5, 21, 28, 29, 30, 31, and 34 under 35 U.S.C. § 103(a) is improper because the Examiner has failed to establish a *prima facie* case of obviousness.

Where the Examiner asserts that it would have been obvious to combine teachings from two or more references to obtain the claimed invention, the Examiner must determine whether there is "an apparent reason to combine the known elements in the fashion claimed by the patent at issue." *KSR Int'l Co.*, 127 S. Ct. at 1740-41. Appellants respectfully assert that there is no reason to combine the teachings of Zohmann with the teachings of Kreuzer et al; or the teachings of Zohmann with the teachings of Smith et al. or the teachings of Zohmann with the teachings of Gribbons et al in the manner asserted by the Examiner, or in any other way that would arrive at a method as recited in claims 5, 21, 28, 29, 30, 31, and 34.

First, the Examiner has not resolved the level of ordinary skill in the art as required under M.P.E.P., § 2141 II. The rejection first fails for this reason.

Second, Appellants respectfully disagree that a *prima facie* case of obviousness has been established because the Examiner is combining the prior art references based on impermissible hindsight. At most, the instant rejections propose a combination of elements by improperly picking and choosing disparate elements from distinct references, which can only be a hindsight attempt to gather elements for bringing them together with the benefit of Appellants' disclosure as a guide.

As provided for by the Office's own guidelines, in order to make an obviousness rejection such as that set forth in the Final Office Action, the Office "must resolve the Graham factual inquiries". *See, e.g.,* M.P.E.P., § 2143 A(1) ("Examples of Basic Requirements of a Prima Facie Case of Obviousness"). Contrary to the Office's own guidelines, however, the instant obviousness rejections never resolved what the level of ordinary skill in the pertinent art was at the time of the invention, which was required. *See,* M.P.E.P., § 2141 II.

Moreover, in making its rejections, the Examiner did not explicitly articulate under what rationale the legal conclusion of obviousness is supported, as required by KSR. *See, e.g.,* M.P.E.P., § 2142. Appellants are left to guess what rationale the Examiner may have used from the list of exemplary rationales cited under M.P.E.P., § 2143. Assuming that the Office has chosen Rationale A ("Combining Prior Art Elements According to Known Methods to Yield Predictable Results") the Office failed to articulate a finding that one of ordinary skill in the art could have combined the elements as claimed by known methods, and that, in combination, each element merely performed the same function as it does separately. *See, e.g.,* M.P.E.P., § 2143 A(2). In fact, the Examiner cannot do so in the instant case because elements of Appellants' claims do not merely perform the same function as they allegedly separately did in the cited references. The Office's guidelines, however, specifically require the Office to make such a finding. *Id.*

The Office's non-compliance with its own rules in this regard would appear to confirm Appellants' position that a *prima facie* case of obviousness has not been established. Of course, Appellants are entitled to rely upon the statutes, Rules of Practice, and provisions of the M.P.E.P.

in prosecuting their patent application. *In re Kaghan*, 387 F.2d 398, 401, 156 USPQ 130, 132 (CCPA 1967).

i. The Rejection of Claims 5 and 21

The rejection of Claims 5 and 21 under 35 USC 103 is illustrative of the lack of motivating rationale for the combination of references relied upon by the Examiner. These claims are rejected in view of a combination of Zohmann and Kreuzer et al. Examiner makes several allegations supporting its rationale to motivate the combination of these two references. First, in support of the combination of Zohmann and Kreuzer et al, the Examiner alleges that it would have been obvious to one skilled in the art to "modify the friction fit connection of Zohmann with a luer lock connector as taught by Kreuzer et al to provide an improved and more secured connection between the catheter and the needle." *See Final Office Action* at page 7. Thus, the only support or evidence that the Examiner alleges for motivation to combine Zohmann with Kreuzer et al is a paraphrased restatement of an element from claim 5 (i.e., to provide a connection). Applicants respectfully submit that the Examiner's reasoning is inadequate under the provisions of 35 USC 103. Furthermore, as noted above, Zohmann fails to teach such a pencil point tip. Kreuzer et al likewise fails to teach a support needle having such a pencil point tip. Instead of a pencil point, non-cutting tip Kreuzer et al teaches a beveled tip 23. See FIG. 2. It follows that with respect to claims 5 and 21 a combination of Zohmann with Kreuzer et al would not teach a support needle having a pencil point tip. Accordingly, the rejection of claims 5 and 21 over Zohmann in view of Kreuzer et al is not supported under 35 USC §103(a).

ii. The Rejection of Claims 28, 29 and 34:

In support of combining Zohmann with Smith et al the Examiner asserts "[i]t would have been obvious to one skilled in the art to combine the material of Smith et al with the system of Zohmann et al because medical grade plastics were well known at the time of invention and the use of a known material is a design choice that would have been obvious to anyone of ordinary skill in the art. It would have been obvious to combine the outer catheter design of Smith et al with the system of Zohmann et al in order to provide a device that is less damaging to the patient upon insertion." *See Final Office Action* at page 7. Again, the only support or evidence that the Examiner alleges for motivation to combine Zohmann with Smith et al is a paraphrased restatement of the elements from claim 28, 29 and 34. As such, the Examiner is merely picking and choosing elements from disparate art and then restating the elements of the referenced claims as a motivation for combining those elements. Applicants respectfully submit that the Examiner's failure to provide an adequate motivation to combine the cited references constitutes reversible error. Furthermore, the combination of Zohmann and Smith et al fails to teach all of the structural limitations of claims 28, 29 and 34. Each of these claims requires a hollow support needle having a pencil point, non-cutting tip. As indicated above, Zohmann neither teaches nor suggests such a tip. Although Smith et al teaches a stylet 26 having a pointed tip 72 (FIG. 11), Smith et al does not teach a hollow support needle having a pencil point tip wherein the support needle defines a lumen dimensioned to receive a stylet.

iii. The Rejection of Claims 30 and 31

The rejection of Claims 30 and 31 relies on a combination of references. The motivation for making this combination fails to meet the test of KSR. The motivation alleged in the Final Office Action for combining Zohmann with Gribbons et al, namely the placement of a flat ribbon

internal spring or metal band in the first end of the flexible needle catheter to stabilize the tip, does not support a combination of the references unless it is also considered in view of Applicant's specification, which constitutes improper hindsight. The only apparent, objective reason for combining Zohmann, Kreuzer et al, Smith et al and Gribbons et al are the suggestions of Applicant's specification. Without the teachings found in Applicant's specification and claims, a person of skill in the art would not combine the identified references. The use of Applicant's specification to motivate a combination of references is improper and does not support a *prima facie* obviousness rejection.

Finally, appellants respectfully submit that none of the combinations posited by the Examiner teach all of the claim elements of any of the rejected claims. All of the claims rejected under 35 USC §103(a) require a needle having a pencil point, non-cutting tip. As noted above, Zohmann fails to teach such a pencil point tip. Gribbons et al fails to teach a support needle having a pencil point tip. It follows that any combination of Zohmann with Gribbons et al would likewise fail to teach a support needle having a pencil point tip. It follows that the rejection of claims 30 and 31 over Zohmann in view of Gribbons et al is not supported under 35 USC §103(a).

For each of the reasons set forth above, Appellants respectfully assert that there is no reason to combine the teachings of Zohmann with the teachings of Kreuzer et al, Smith et al or Gribbons et al in the manner asserted by the Examiner, or in any other way that would arrive at the structures as recited in claims 5, 21, 28, 29, 30, 31, and 34. As such, a *prima facie* case of obviousness has not been established.

In view of the foregoing, Appellants respectfully submit that 5, 21, 28, 29, 30, 31, and 34 are allowable over Zohmann and the various cited references. Applicants therefore request that the instant rejections be overturned.

1) CLAIMS APPENDIX

A copy of claims 1 through 34 is appended hereto as "Appendix A."

2) EVIDENCE APPENDIX

A copy of each of the following references is appended hereto in "Appendix B."

- U.S. PGPub 2002/0099335 A1 to Zohmann.
- U.S. Patent No. 5,116,323 to Kreuzer et al.
- U.S. Patent No. 5,250,035 to Smith et al.
- U.S. PGPub 2005/0070881 to Gribbons et al.

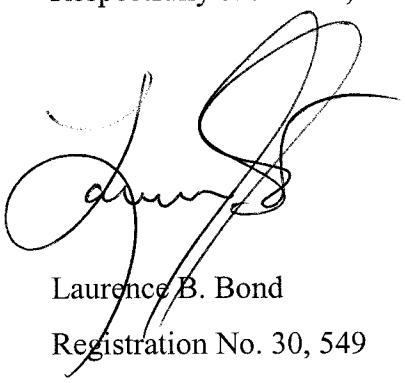
3) RELATED PROCEEDINGS APPENDIX

None.

CONCLUSION

Appellant respectfully submits that claims 1-6, 8. 9. 12. 14-18, 20, 21, 23, 25 and 27-34 are allowable over the cited references of record. Appellant respectfully requests that the rejections of the aforesaid claims be reversed.

Respectfully submitted,



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Date: 27 January 2010

Document in ProLaw

APPENDIX A

Listing of the Claims:

1. (Rejected) A flexible spinal needle catheter assembly comprising:

a flexible needle catheter, said flexible needle catheter defining a hollow bore for conveying medicating agent therethrough, said bore extending through a length of said flexible needle catheter, said flexible needle catheter having a proximal end which defines a leading edge;

a support needle releaseably secured to said flexible needle catheter, said support needle being disposed within said hollow bore of said flexible needle catheter, said support needle having a first end which defines a pencil point, non-cutting piercing point configured for penetrating the dura mater of a patient, said support needle having an outside diameter sized so that upon withdrawal of the flexible spinal needle catheter assembly from a dura mater of a spine of a patient, subsequent to an insertion of said assembly through the dura mater, a puncture opening produced by said insertion is of dimensions which permit the dura mater substantially to reseal said puncture opening formerly occupied by the flexible spinal needle assembly within said dura mater, said support needle defining a hollow lumen which extends along a length of said support needle and an opening, defined proximate said first end, which communicates the environment with said lumen, said support needle being dimensioned such that said first end of said support needle is positioned outside of said bore of said flexible needle catheter, said non-cutting piercing point and said opening being positioned outside of said bore, and

a solid stylet, releaseably secured within said lumen, said stylet being positioned in a first condition to preclude access from the environment to said lumen through said opening .

2. (Rejected) The flexible spinal needle assembly of claim 1, wherein said leading edge of said flexible needle catheter is positioned proximate said pencil point tip .

3. (Rejected) The flexible spinal needle assembly of claim 1, wherein said flexible needle assembly has a tip configured and arranged to provide a feedback signal to indicate dural puncture.

4. (Rejected) The flexible spinal needle assembly of claim 1, wherein: a rear end of said support needle carries a support hub having a first attach structure; and a proximal end of said flexible needle carries a flexible needle hub having a second attach structure configured to removably attach to the first attach structure carried by said support hub.

5. (Rejected) The flexible spinal needle assembly of claim 4, wherein the first and second attach structures comprise a luer lock type connection.

6. (Rejected) The flexible spinal needle assembly of claim 4, wherein said flexible needle hub is configured for substantially unobtrusive attachment to a patient's skin by way of an intermediary adhesive element.

7. (Withdrawn) The flexible spinal needle assembly of claim 4, wherein said flexible needle hub is configured for attachment to medical fluid transfer equipment by an attachment structure to form a connection generally perpendicular to a direction of needle insertion.

8. (Rejected) The flexible spinal needle assembly of claim 1, wherein: a rear end of said support needle carries a support hub; and a proximal end of said flexible needle carries a flexible needle hub having a detach structure configured to detach the flexible needle hub from the support hub.

9. (Rejected) The flexible spinal needle assembly of claim 1, wherein: a proximal end of said flexible needle carries a flexible needle hub; and a rear end of said support needle carries a support hub having a detach structure configured to detach the flexible needle hub from the support hub.

10. (Withdrawn) The flexible needle assembly of claim 1, wherein said flexible needle comprises a conduit formed from a first material and radially reinforced at a distal end by a second material.

11. (Withdrawn) The flexible spinal needle assembly of claim 10, wherein said second material is selected from the group comprising a stainless steel wire and a ribbon spring.

12. (Rejected) The flexible spinal needle assembly of claim 1, wherein said flexible needle comprises a force absorbing structure to prevent kinking when the flexible needle is overly flexed.

13. (Withdrawn) The flexible spinal needle assembly of claim 12, wherein said force absorbing structure comprises a ribbon spring.

14. (Rejected) The flexible needle assembly of claim 12, wherein said force absorbing structure comprises a kink sleeve disposed on a portion thereof.

15. (Rejected) The flexible spinal needle assembly of claim 1, wherein said stylet is slidably mounted in said support needle.

16. (Rejected) A flexible spinal needle assembly for inserting a distal end of a flexible spinal needle through dura mater into a spine of a patient, said flexible spinal needle assembly comprising:

a flexible needle;

a support needle having a proximal end and a pencil point non-cutting piercing point at a distal end, said support needle being releaseably secured to said flexible needle to resist relative motion between a distal end of said flexible needle and said pencil point non-cutting piercing point during insertion of said flexible spinal needle assembly into a patient;

wherein said flexible needle is carried exterior to said support needle to expose said non-cutting piercing point when said assembly is positioned for said inserting.

17. (Rejected) The flexible spinal needle assembly of claim 16, wherein said flexible needle has an exterior diameter configured such that withdrawal of said flexible needle from said dura mater, subsequent to insertion of the flexible needle assembly therethrough, permits said dura mater substantially to reseal a space formerly occupied by said flexible needle, and a tip and

a flexible needle body of said flexible needle are of substantial elongated extent to be further extendable into the dura mater upon extraction of said support needle.

18. (currently amended) The flexible spinal needle assembly of claim 17, wherein: said proximal end of said support needle carries a support hub having a first attach structure; a proximal end of said flexible needle carries a flexible needle hub having a second attach structure configured to interface in removable interference with said first attach structure carried by said support hub.

19. (Withdrawn) The flexible spinal needle assembly of claim 16, wherein said flexible needle further comprises a radially reinforcing material located at a distal end of said flexible needle, said reinforcing material resisting peel-back of said flexible needle from said support needle.

20. (Rejected) The flexible spinal needle assembly of claim 16, having a distal end of said assembly being constructed to provide a perceptible feedback signal when said distal end of said flexible needle penetrates said dura mater.

21. (Rejected) The flexible spinal needle assembly of claim 16, characterized in said flexible needle hub further being configured for attachment to medical fluid transfer equipment having structure to form a luer lock type connection.

22. (Withdrawn) The flexible spinal needle assembly of claim 16, wherein a flexible needle hub is configured for attachment to medical fluid transfer equipment by an attachment structure to form a connection generally perpendicular to a direction of flexible needle insertion.

23. (Rejected) The flexible spinal needle assembly of claim 16, wherein said flexible needle comprises a kink sleeve disposed on a portion thereof, said kink sleeve configured to prevent kinking of said flexible needle when said flexible needle is extended beyond the substantial flexure point during use.

24. (Canceled).

25. (Rejected) A flexible spinal needle comprising:

a support needle having a pencil point, non-cutting piercing tip;

a flexible needle body comprising an elongated hollow tube, said flexible needle body configured to be slidably mounted on an exterior of said support needle; and

a kink sleeve disposed on a portion of said flexible needle body, said kink sleeve being configured to prevent kinking of said flexible needle body, when said flexible needle body is bent beyond a flexible structural resilience thereof during use.

26. (Withdrawn) A flexible spinal needle comprising: a flexible needle body comprising an elongated hollow tube, said flexible needle body configured to be slidably mounted on an exterior of a support needle; a flexible needle hub configured for attachment to medical fluid

transfer equipment by an attachment structure to form a connection generally perpendicular to a longitudinal axis of said flexible needle body.

27. (Rejected) A flexible spinal needle assembly comprising:

a support needle comprising a first end defining a pencil point, non-cutting piercing point, and a hollow bore with an opening proximate said first end allowing access to said bore; and

a flexible needle slidably mounted on an exterior portion of said support needle such that said first end of said support needle protrudes from said flexible needle exposing said pencil point, non-cutting piercing point and said opening, wherein said flexible needle has sufficient transverse flexibility to accommodate patient torso bending movement so as to substantially reduce a patient's awareness of the presence of the flexible needle.

28. (Rejected) The flexible spinal needle assembly of claim 27 wherein the flexible needle comprises a medical grade plastic material and a tip extending axially from the flexible needle body of said flexible needle of substantial extent to be further extendable into the dura mater upon extraction of said support needle.

29. (Rejected) The flexible spinal needle assembly of Claim 1 wherein said first end of said flexible needle catheter is tapered into a curve to blend smoothly into the outer surface of said support needle.

30. (Rejected) The flexible spinal needle assembly of Claim 1 wherein said first end of

said flexible needle catheter is reinforced with a flat ribbon internal spring disposed within a wall of said flexible needle.

31. (Rejected) The flexible spinal needle assembly of Claim 1 wherein said first end of said flexible needle catheter is reinforced with a metal band.

32 (Rejected) The flexible needle catheter assembly of Claim 1 wherein said flexible needle catheter is disposed on an outer surface of said support needle.

33. (Rejected) The flexible needle catheter assembly of Claim 1 wherein a leading edge of said flexible needle catheter is positioned adjacent to said opening in said support needle.

34. (Rejected) The flexible needle catheter assembly of Claim 33 wherein said leading edge is positioned perpendicularly to a longitudinal axis of said support needle.

APPENDIX B

APPENDIX B

US 20020099335A1

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(54) **SPINAL NEEDLE**

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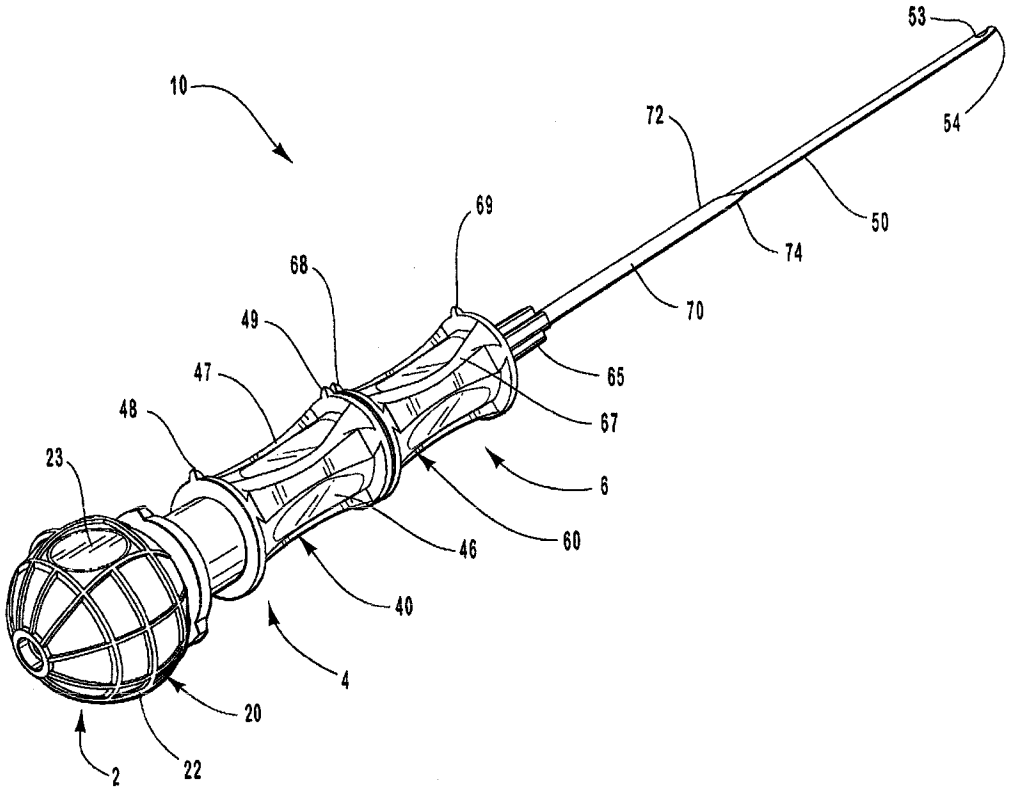
(52) **U.S. Cl.** **604/198**; 604/253

(57) **ABSTRACT**

The present invention is directed toward an improved spinal needle. A needle hub is disposed about a proximate end of a hollow needle. The needle hub side port indicators provide visual and tactual verification by a user of the orientation of the side port on the needle. The needle hub also includes a window with a magnified view. The invention provides a stylet cap disposed about a proximate end of a stylet that freely slides inside the hollow needle and needle hub. The stylet cap forms a pressure fit with the needle hub, and can be engaged in the pressure fit from any axial orientation.



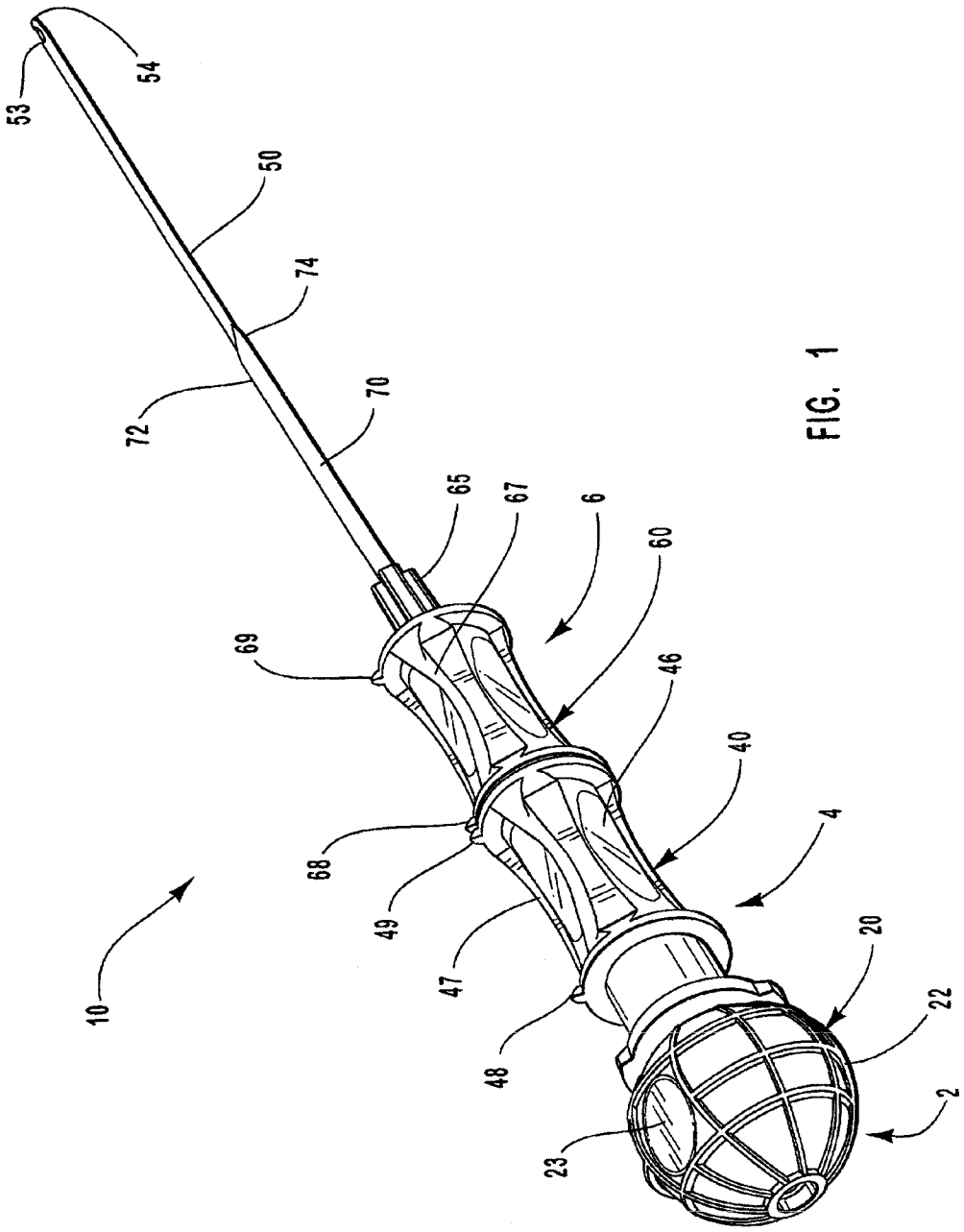


FIG. 1

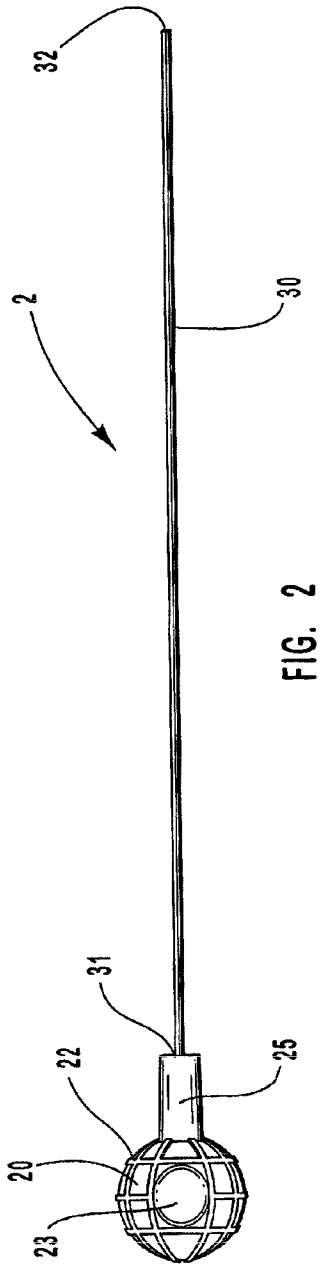


FIG. 2

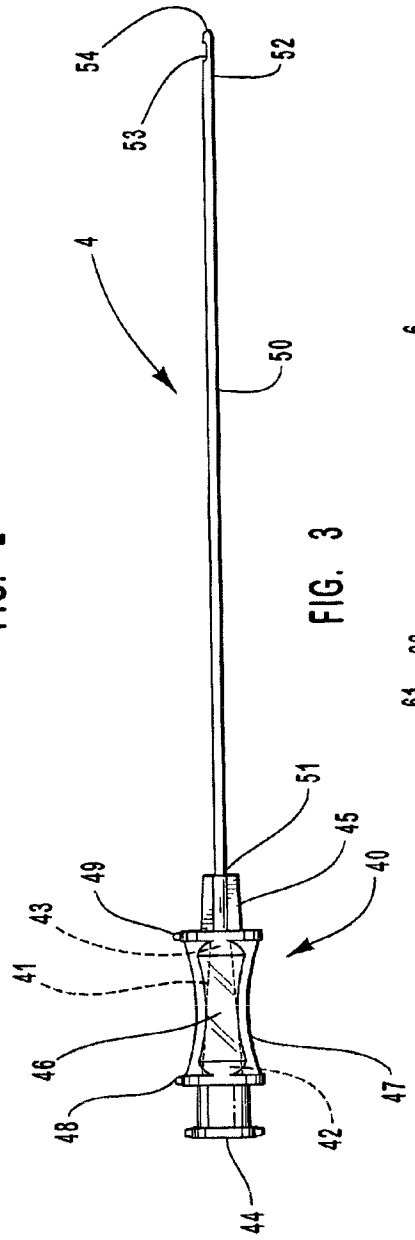


FIG. 3

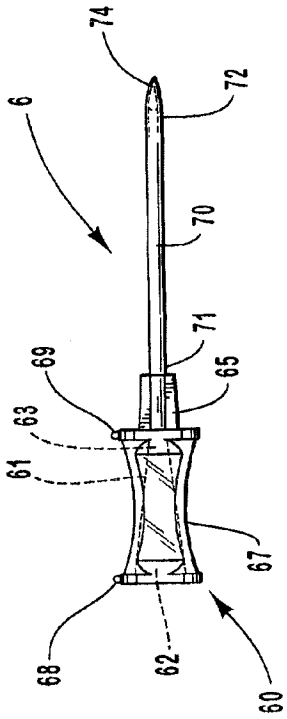


FIG. 4

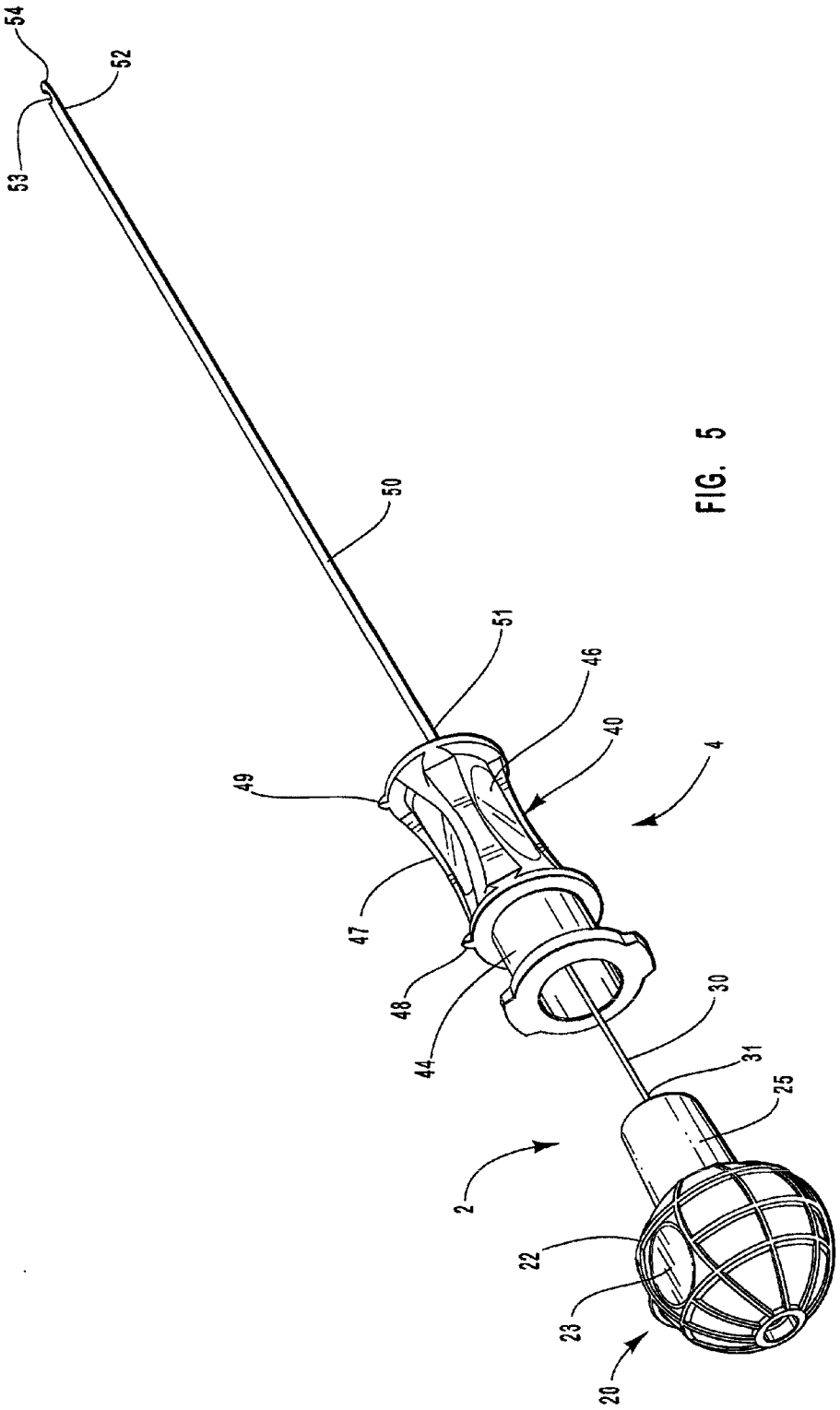


FIG. 5

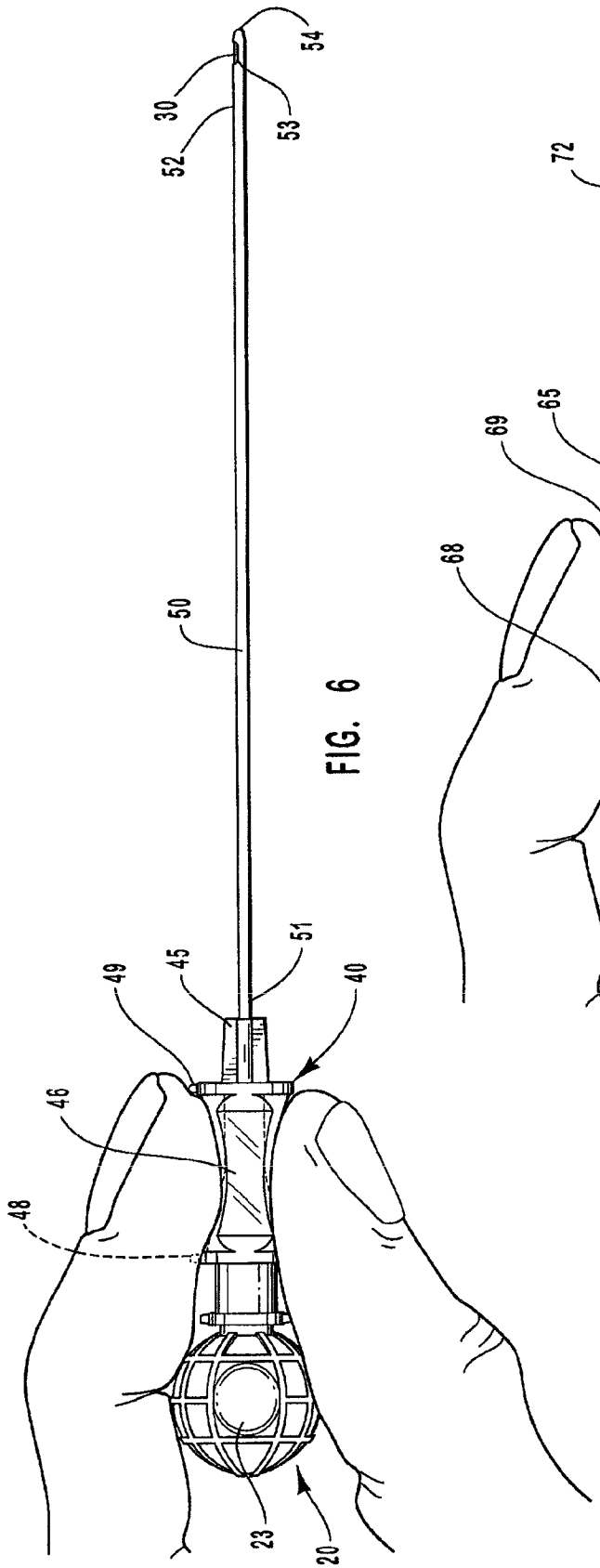


FIG. 6

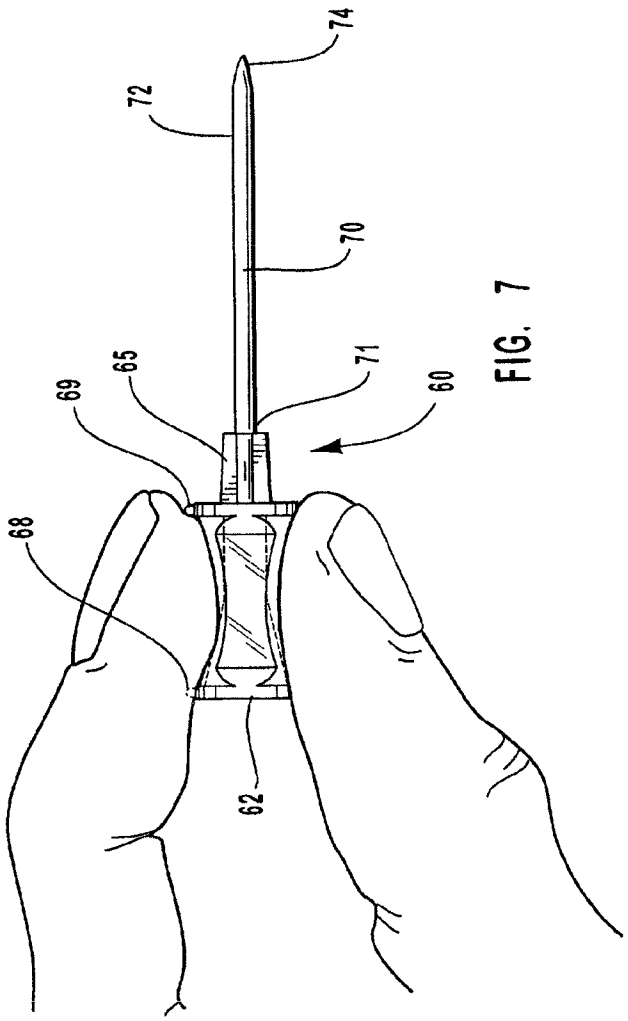


FIG. 7

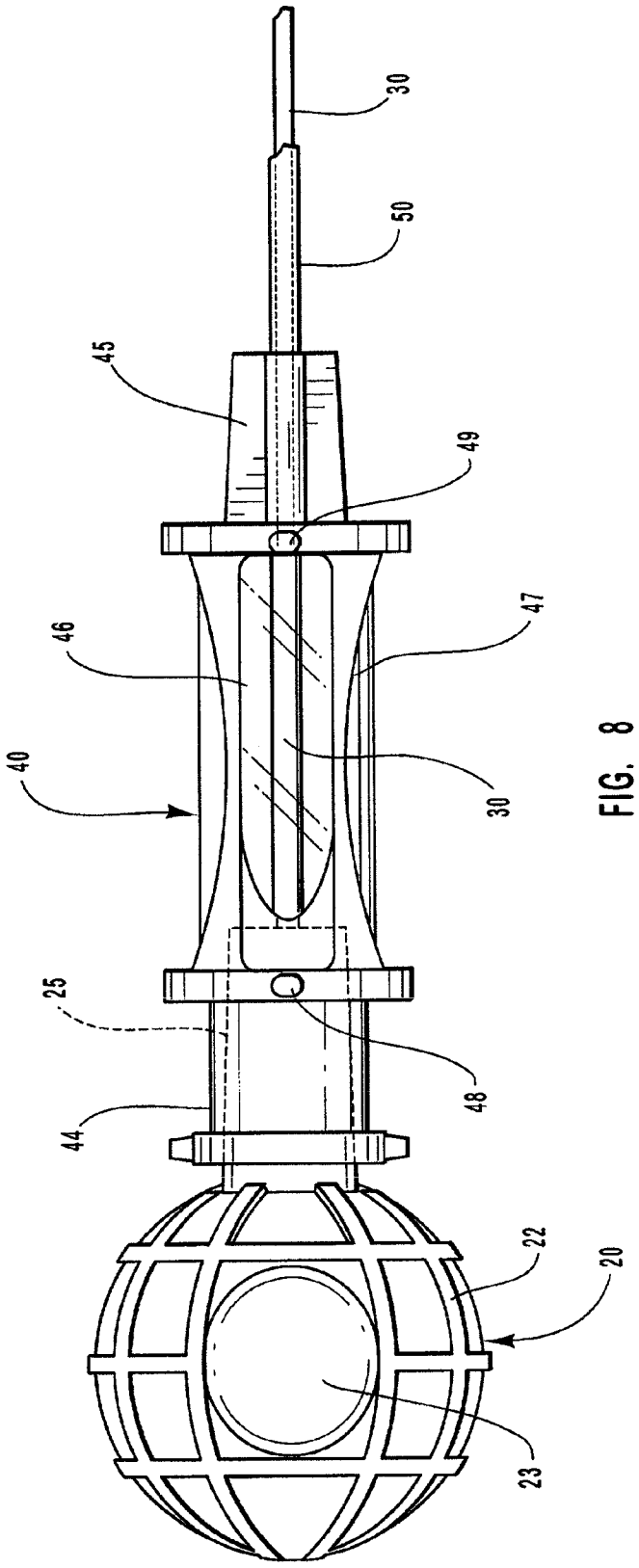


FIG. 8

SPINAL NEEDLE

BACKGROUND

[0001] 1. Field of the Invention

[0002] This invention relates to innovative needles for facilitating lumbar puncture procedures generally and, more particularly, to a novel, atraumatic needle apparatus and method for reducing loss of cerebral spinal fluid (CSF) during such procedures.

[0003] 2. Background

[0004] Spinal anesthesia is one of the most frequently employed methods of regional anesthesia. This regional anesthesia is accomplished by the temporary interruption of nerve transmission using a local anesthetic injected into the readily identifiable subarachnoid space. The ensuing anesthesia is predictable, occurs rapidly, and is associated with profound muscle relaxation. The patient may be wide awake, or if preferred, the anesthetic may be supplemented with varying amounts of sedative-tranquilizers. Spinal anesthesia is particularly useful for surgery involving the lower extremities, pelvis, perineum, and lower abdomen.

[0005] The spinal column, which surrounds the spinal cord, is formed by a series of vertebrae separated by cartilaginous intervertebral disks and united by a series of ligaments. The body of each vertebra bears the weight of the patient and forms the base of the neural arch. The arch, which surrounds the spinal cord, is made up of a pedicle and lamina on each side. Between the laminae of each vertebra there is a posterior opening in the vertebral canal. It is through this opening that a spinal needle is passed when performing a subarachnoid block.

[0006] In adults the spinal cord varies in length from 40 to 45 cm. and ends at various levels of the vertebral column depending on the age of the patient. In the newborn, the spinal cord extends to the third lumbar vertebra, but in the adult it usually ends at the lower border of the first lumbar vertebra because the spinal cord does not grow as much as the vertebral column. Thirty-one pairs of symmetrically arranged spinal nerves are each attached to the spinal cord by an anterior and posterior root. Because the spinal cord is shorter than the vertebral column, the spinal cord segments in adults do not lie opposite their corresponding vertebrae. The spinal nerve roots must travel obliquely in a caudad direction to reach their respective intervertebral foramina. The roots of the lumbar, sacral, and coccygeal nerves comprise the cauda equina and are necessarily the largest and longest in order to reach their intervertebral foramen. The greater size of these nerve roots provides a larger surface area to be exposed to the action of local anesthetics, thus allowing more rapid onset of anesthesia.

[0007] The spinal cord is covered by three membranes or meninges. The dura mater (the outennost membrane) is the downward continuation of the meningeal layer of the cranial dura mater. The middle of the three coverings, the arachnoid is a thin membrane closely adherent to the dura mater. The dura and the arachnoid are in such close contact that usually it is not possible to puncture the dura without also piercing the arachnoid. Nevertheless, on rare occasions, the tip of the conventional epidural or spinal needle may accidentally enter the subdural space. Local anesthetic inadvertently injected into the subdural space will diffuse poorly and result in inadequate contact with the nerve roots. Poor or absent anesthesia may ensue. Should subdural placement occur during an attempted epidural anesthetic, the improper position of the needle may not be recognized and the injection of an epidural dose of local anesthetic may result in a much higher block than anticipated.

[0008] The innermost membrane, the pia mater, is a thin, delicate, highly vascular membrane closely adherent to the spinal cord. The space surrounding the pia is filled with cerebrospinal fluid and is enclosed externally by the arachnoid. hi addition to spinal fluid, this space contains the spinal nerve roots and the main blood vessels of the central nervous system. In the cervical and thoracic regions, the space is only about 3 mm deep, but below the lower border of the first lumbar vertebra, where the spinal cord usually ends, the space has a diameter of about 14 to 15 mm.

[0009] A typical spinal anesthetic delivery device comprises three components. A sharp, hollow introducer component a few centimeters in length that is used to puncture the skin, a more blunt hollow needle component several centimeters in length that is slideably disposed within the hollow introducer to allow the caregiver to delicately pierce the dura membrane, and a stylet component that is slideably disposed within the needle to selectively occlude the needle and control the flow of fluid therein. The introducer and needle components both have hubs on their proximate ends. The hubs act as handles or grips to facilitate manipulation of the introducer and needle.

[0010] Delivering spinal anesthesia may be accomplished using a lumbar puncture procedure. The lumbar puncture generally involves the following steps:

[0011] (1) Placing the patient receiving the procedure in the lateral decubitus position on the edge of the bed with the patient's back exposed to the caregiver carrying out the procedure;

[0012] (2) Placing the patient in a fetal like position with the head supported so that the head and spine are parallel to the bed and the knees are to the chest;

[0013] (3) Marking the posterior iliac crest and palpate the L4 spinous process;

[0014] (4) Anesthetizing the patient's skin in preparation for inserting an introducer and spinal needle;

[0015] (5) Inserting the introducer at the marked puncture point;

[0016] (6) Advancing the needle slowly through the introducer until the dura membrane is breached. A distinct "pop" may be heard when the membrane is pierced. The needle should be inserted approximately two centimeters into the skin.

[0017] (7) After the dura membrane is pierced, withdrawing the stylet disposed within the needle as the needle is advanced to verify the presence of CSF flowing back out of the needle;

[0018] (8) Injecting the anesthetic through the needle to induce the anesthetic block;

[0019] (9) Withdrawing the needle and introducer without replacing the stylet; and

[0020] (10) Dressing the puncture site with a bandage.

[0021] A spinal needle 9 cm long is usually adequate for lumbar puncture, but longer ones (10-915 cm) are available for the occasional obese patient or difficult paramedian approach. The removable, close-fitting stylet helps stiffen the needle and prevents coring of the tissue. Commonly, two sizes of spinal needles are used, 22-27 gauge. The larger diameter 22 gauge needle is easier to direct and renders the characteristic feel of the various ligaments penetrated easier to appreciate. However, the incidence of postspinal headache is increased with the larger needle, particularly if the larger needle is also equipped with a standard point which is a cutting bevel.

[0022] A postdural puncture headache is the most common postoperative complication of spinal anesthesia. The incidence increases with the larger spinal needles and those with a cutting bevel at the tip but decreases with increasing patient age. Postdural puncture headache also occurs more commonly in women than in men, and more often in pregnant women than in nonpregnant women. The headache is positional in that it comes on in the upright position and is relieved or at least improved in the recumbent position.

[0023] The causative mechanism of the postdural puncture headache is believed to be associated with the continuing leakage of cerebrospinal fluid (CSF) through the dural opening left by the spinal needle. The leakage of CSF causes a decrease in CSF pressure which, in turn, produces compensatory cerebral vasodilation. Bringing the patient into the erect position also results in traction on the pain-sensitive, dilated blood vessels. Accordingly, conservative therapy for the postdural puncture headache consists of bed rest and analgesics.

[0024] Various preventive measures for the postdural puncture headache have been advocated. The common practice of keeping the patient supine for 4 to 24 hours after lumbar puncture has been shown to be ineffective. For a standard point needle having a cutting bevel at its tip, insertion of the needle with the bevel parallel to the longitudinal fibers of the dura appears to produce a smaller rent in the dura with a lower incidence of headache. Pencil point needles such as the commercially available Whitacre and Sprotte needles also have a lower incidence of headaches. These pencil-point needles have a closed pencil point created when the open end of the needle is swaged closed, as the name implies, like a pencil point or, more accurately, with a conical apex. This conical apex is believed to spread, rather than cut, the predominately longitudinal dural fibers and, on removal of the needle, the resulting dural hole should be smaller and seal off more rapidly. Indeed, studies have shown that the incidence of postspinal headache when a 22 gauge conical apex needle is used is comparable to that following use of the much smaller 26 gauge, bevel needle.

[0025] In an attempt to minimize leakage of CSF, an available procedure is to create what is known as a blood patch. This is done by obtaining 10 to 20 cc of blood from the patient and injecting this volume of blood into the tissue adjacent the puncture site of the spinal needle. This relatively large volume of blood is required since it is virtually impossible for the health care professional to exactly position the blood patch directly over the original puncture site. In effect, therefore, the blood patch is designed to seal the dural puncture thereby significantly minimizing the frequency of the postdural headache.

[0026] Another disadvantage to the presently available pencil-point-tip spinal needles is that the sides of the tip are generally straight in a true cone configuration. Thus, a relatively abrupt shoulder is formed as a ridge at the juncture between the sloped sides of the conical tip and the cylindrical side walls of the body of the needle. It is currently postulated that this relatively abrupt change in the profile of the needle excessively distorts the dura and thereby contributes to the presence of a post puncture hole in the dura.

[0027] Once the needle has punctured the dura, excessive movement of the needle may undesirably increase the size of the puncture hole of further traumatize surrounding tissue. For example, if the needle side port is improperly positioned because the caregiver was unable to accurately gauge the orientation of the sideport, during insertion, the caregiver may attempt to rotate and adjust the needle to properly position the side port to deliver the drug. This additional movement may undesirably increase the size of the dura puncture hole or increase trauma to the tissue. Likewise, if the caregiver is unable to see whether there has been a return of CSF or some other fluid into the needle hub, the care giver may have to move or reposition the needle in order to verify CSF return or the pressure of the fluid. Moreover, if the stylet is difficult to handle or troublesome to secure in place, excessive manipulation of the stylet can cause unnecessary displacement of the needle resulting in additional trauma to the dura and increasing the size of the dura puncture hole.

[0028] It would be advantageous to provide an improved needle for facilitating lumbar puncture procedures and for reducing the likelihood of undesired CSF leakage caused by unintended enlargement the lumbar puncture hole or trauma to surrounding tissue. It would further be and advantage to provide a needle for facilitating lumbar puncture whereby the orientation of the side port is easily verified, the return of the CSF is readily visible through the needle hub and the stylet is easily inserted and manipulated.

SUMMARY AND OBJECTS OF THE INVENTION

[0029] This invention is an improved needle for facilitating lumbar puncture procedures. More particularly, the invention is a novel, atraumatic needle apparatus for reducing loss of CSF through the dura puncture hole. The apparatus comprises a sharp, hollow introducer component a few centimeters in length that is used to puncture the skin, having raised tip indicators disposed upon the introducer hub; a more blunt, hollow needle component several centimeters in length that is slideably disposed within the hollow introducer, the needle hub having raised side port indicators and a magnifying window for viewing the return of fluid in the hub; and a stylet component that is slideably disposed within the hollow needle to selectively occlude the needle and control the flow of fluid therein. The introducer and needle components both have relatively small transparent hubs on their proximate ends. The hubs act as handles or grips to facilitate manipulation of the introducer and needle and allow the caregiver to view fluids passing into or out of them.

[0030] It is, therefore, a primary object of this invention to provide improvements in spinal needle apparatus.

[0031] Another object of this invention is to provide a spinal needle apparatus with means for visually and tactually verifying the orientation of the needle side port.

[0032] It is yet another object of one embodiment of the present invention to provide a spinal needle apparatus with means for facilitating visual verification of CSF return.

[0033] It is yet another object of one embodiment of the present invention to provide a spinal needle apparatus having a stylet that is easily inserted and manipulated.

[0034] These and other objects and features of the present invention will become more readily apparent from the following description in which preferred and other embodiments of the invention have been set forth in conjunction with the accompanying drawing and appended claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[0035] The foregoing and other objects and features of the present invention will become more fully apparent from the following description and appended claims, taken in conjunction with the accompanying drawings. Understanding that these drawings depict only typical embodiments of the invention and are, therefore, not to be considered limiting of its scope, the invention will be described and explained with additional specificity and detail through the use of the accompanying drawings in which:

[0036] **FIG. 1** shows a perspective of the needle apparatus;

[0037] **FIG. 2** shows a side view of the stylet

[0038] **FIG. 3** shows a side view of the needle component

[0039] **FIG. 4** shows a side view of the introducer without the sheath

[0040] **FIG. 5** shows a perspective view the stylet cap and stylet partially inserted and in alignment with the needle hub;

[0041] **FIG. 6** shows the needle hub with the user's finger in contact with the raised portions for verifying the orientation of the side port;

[0042] **FIG. 7** shows the introducer hub with the user's finger in contact with the raised portions for verifying the orientation of the beveled tip; and

[0043] **FIG. 8** shows the needle hub with a magnifying window showing the stylet in magnified view.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0044] It will be readily understood that the components of the present invention, as generally described and illustrated in the figures herein, could be arranged and designed in a wide variety of different configurations. Thus, the following more detailed description of the embodiments of the system and method of the present invention, and represented in **FIGS. 1 through 8**, is not intended to limit the scope of the invention, as claimed, but is merely representative of the presently preferred embodiments of the invention.

[0045] The presently preferred embodiments of the invention will be best understood by reference to the drawings, wherein like parts are designated by like numerals throughout.

[0046] The present invention relates to an improved spinal anesthesia needle apparatus. As shown in **FIG. 1, a** spinal anesthesia needle apparatus **10** comprises three main components: a stylet component **2** further comprising a stylet cap **20** and stylet **30**; a needle component **4** further comprising a needle hub **40** and a hollow needle **50**; and an introducer component **6** further comprising an introducer hub **60** and an hollow introducer **70**.

[0047] As shown in **FIG. 2**, stylet component **2** comprises stylet **30** having a proximate end **31** and a distal end **32**. The term proximate as used herein connotes proximate to the "main body" of needle apparatus **10**, or in other words, nearer the portion of needle apparatus **10** that connects to a syringe. The term "distal" connotes a position removed from the main body of needle apparatus **10** or in other words, nearer the tip of needle apparatus **10**. Stylet **30** has a diameter and a length. The length and diameter of stylet **30** are sufficient to occlude hollow needle **50** when stylet **30** is inserted into needle **50**.

[0048] Stylet cap **20** has a generally spherical shape with raised portions **22** and flat areas **23** distributed throughout the surface of spherical stylet cap **20**. The generally uniform shape of stylet cap **20** allows stylet cap **20** to be gripped with a conventional or uniform grip from almost any angle. Raised areas **22** and flat portions **23** of stylet cap **20** allow stylet cap **20** to be manipulated more easily, even when the user is wearing surgical gloves. Stylet cap **20** has a cap nose **25** component disposed around stylet **30** where stylet **30** communicates with stylet cap **20**. Cap nose **25** is frusco-conical in shape with the broader base of the cone being adjacent to stylet cap **20**. The diameter of nose **25** allows it to slide into and fit securely with hollow needle hub **40**, as shown in **FIG. 5**. Stylet cap **20** and needle hub **40** create a pressure fit that allows stylet **30** to be rotated around its access and still be secured by pressure fit with needle hub **40**. Stylet cap **20** does not need to be rotated to a particular orientation to create the pressure fit.

[0049] Stylet component **2** of the present invention offers several advantages. First, stylet **30** reinforces needle **50** as needle **50** is being inserted positioned or retracted. Second, as mentioned above, stylet **30** closes side port **53** of needle **50**. Occlusion of site port **53** is a particular problem when stylet **30** is being repositioned during the procedure. Also, it is possible for side port **53** to cause trauma to the dura if side port **53** is left open during insertion. Additionally, the stylet also indicates whether needle **50** has been bent upon withdrawal.

[0050] In addition to the advantages above, stylet **30** of the present invention provides a stylet cap **20** that makes it easier to see and manipulate the stylet than prior art stylets cap. Stylet **30** reduces the likelihood that the anesthesiologist will mishandle or fumble with the stylet and thereby reduces the likelihood of unnecessarily traumatizing tissue, reduces the likelihood of headache due to a decrease in pressure of cerebral spinal fluid, and may save the anesthesiologist time. For example, during the procedure, the anesthesiologist may need to withdraw and reinsert needle **50** until he or she can obtain a backflow of spinal fluid through needle **50** into the needle hub **40**. When this backflow is observed, the anesthesiologist may need to promptly reinsert stylet component **2** to occlude side port **53**. Stylet cap **20** of the present invention facilitates the anesthesiologist's efforts

to respond promptly, once the anesthesiologist verified spinal fluid flow through needle **50**. Stylet cap **20** provides improved handling of stylet **30** and allows stylet **30** to be more quickly positioned and stylet **30** does not have to be aligned in a particular position relative to needle hub **40**, like prior art devices.

[0051] Stylet **30** slides inside hollow needle **50** through needle hub **40** until stylet cap **20** contacts needle hub **40**. The nose **25** of the stylet cap **20** slides into and contacts the interior walls of needle hub **40** creating a pressure fit between stylet nose **25** and the broad opening of needle hub **40**. The spherical shape of stylet cap **20** obstructs broad opening **42** of needle hub **40**.

[0052] As shown in **FIG. 3**, needle component **4** of the present invention further comprises needle **50** having a length and diameter suitable for spinal injection and having a rounded tip **54** and side port **53** opening. Needle **50** is hollow and has a rounded tip **54** on the injection (distal) end **52** and a needle hub **40** disposed around the syringe end (proximate end) **51**. Needle **50** has two openings, a side port **53** opening near distal end **52**, opening along the side of the needle, and an intake opening at proximate end **51**.

[0053] Hollow needle hub **40** is disposed around proximate end **57** of needle **50**. Needle hub **40** defines a funnel **41** having two openings, a first narrow opening **43** communicating with the needle intake opening and a wide opening **42** at the hub's proximate end. Nose **25** of stylet cap **20** can be inserted into wide opening **42** of the interior funnel in a pressure fit. The wide opening **42** has a shape corresponding to stylet cap nose **25** to allow such a pressure fit. In one embodiment, wide opening **42** is substantially cylindrical and tubular, allowing a frusco conical shape stylet cap nose **25** to form a pressure fit in wide opening **42**. Needle hub **40** also provides an extended opening **44**.

[0054] Needle hub **40** further comprises a finger grip **47** component disposed about interior funnel **41**. Finger grip **47** has a plurality of sides and has a length and diameter which allows grip **47** to be easily manipulated between the thumb and forefinger. The sides of finger grip **47** can be slightly concave to facilitate handling. Additionally, needle hub **40** has magnifying window **46**. Window **46** reveals the contents of the interior of hub **40** in magnified view. In one embodiment, the interior funnel **41** is magnified so that any fluid passing into or out of funnel **40** is more easily viewed by the user.

[0055] Needle hub **40** also provides a hub nose **45** at the distal end of hub **40** and disposed about the proximate end of needle **50**. Needle hub nose **45** allows needle component **4** to be pressure fit with the proximate opening **62** of introducer component **6**. In one embodiment, hub nose **45** is cross-shaped. Needle hub **40** also provides side port indicators **48** and **49**. Side port indicators **48**, **49** are raised portions of the needle hub **40** that correspond with the relative position of side port **53**, so that orientation of side port **53** can be known when side port **53** is not in view. This allows the user to remain aware of the direction of the release or uptake of fluid through side port **53**. In the preferred embodiment, the side port indicators **48**, **49** are raised from the surface of the needle hub to provide visual and/or tactile and a verification of side port **53** orientation, as shown in **FIG. 6**.

[0056] Needle **50** conducts the flow of liquid from the syringe into the tissues and from the tissues into the syringe. Needle hub **40** allows needle **50** to be manipulated more easily. Needle **50** fits or slides through the hollow introducer hub **60** and through the introducer **70**. Needle nose **45** forms a pressure fitting with a wide opening **62** of introducer hub **60**.

[0057] As shown in **FIG. 4**, introducer component **6** of the present invention further comprises introducer **70** having a length and diameter suitable for spinal insertion and having a beveled tip. Introducer **70** is hollow and has a beveled tip **74** on the insertion (distal) end **72** and an introducer hub **60** disposed around the syringe end (proximate end) **71**. Introducer **70** has two openings, a beveled tip **74** opening near distal end **72**, and a base opening at the base of the introducer at the proximate end **71**.

[0058] Hollow introducer hub **60** is disposed around proximate end **71** of introducer **70**. Introducer hub **60** defines a funnel **61** having two openings, a first, narrow opening **63** at the distal end communicating with introducer **70** and a second wide opening **62** at the introducer hub's proximate end. Needle component **4** is releasably attached to introducer component **6** by means of needle hub nose **45** being inserted into wide opening **62** of interior funnel **61** in a pressure fit. Thus, wide opening **62** has a shape corresponding to needle hub nose **45** to allow such a pressure fit.

[0059] Introducer component **6** further comprises a finger grip **67** disposed about interior funnel **61**. Finger grip **67** has a plurality of sides and has a length and diameter which allows finger grip **67** to be easily manipulated between the thumb and forefinger. The sides of finger grip **67** can be slightly concave to facilitate handling. Additionally, a magnifying window **66** may be disposed within introducer finger grip **67**. Magnifying window **46** reveals the contents of interior funnel **61** of introducer hub **60** in magnified view, such that any fluid passing into or out of the magnified area of interior funnel **61** is more easily viewed by the user, as shown in **FIG. 8**.

[0060] Introducer hub **60** also provides a hub nose **65** at the distal end of the hub **60**, disposed about proximate end **71** of introducer **70**. Introducer hub nose **65** allows introducer **70** to be realeasably attached with a pressure fit to a protective sheath. In one embodiment, hub nose **65** has a cross-form shape section. Introducer hub **60** also provides bevel tip indicators **68**, **69**. Bevel tip indicators **68**, **69** are a raised portion of the introducer hub **65** that correspond to the position of bevel tip **74** so that the position of bevel tip **74** can be known when bevel tip **74** is otherwise not visible. This allows the user to remain aware of the direction and angle of the cutting performed by bevel tip **74**. In the preferred embodiment, bevel tip indicators **68**, **69** are raised from the surface of the problem to provide visual and/or tactile verification of bevel tip **74** position, as shown in **FIG. 7**.

EXAMPLE

[0061] In one embodiment of the present invention, a spinal anesthetic delivery device comprises three components. A sharp, hollow introducer component a few centimeters in length that is used to puncture the skin, a more blunt hollow needle component that is several centimeters in length that is slideably disposed within the hollow introducer to allow the caregiver to delicately pierce the dura membrane, and a stylet component that is slideably disposed

within the introducer to selectively occlude the needle and control the flow of fluid therein. The introducer and needle components both have relatively small transparent hubs on their proximate ends. The hubs act as handles or grips to facilitate manipulation of the introducer and needle and allow the caregiver to view fluids passing into or out of them.

[0062] Using the present invention, a care giver administers a lumbar puncture procedure following the steps typically used in procedures well-known in the art, but includes the advantageous steps of verifying the position of the side port and orienting the side port using side port indicators and the step of verifying the return of CSF and other fluids passing through the needle hub through the magnified window in the hub. Thus, one embodiment of the present invention, a method for spinal anesthesia comprises the steps of: placing the patient receiving the procedure in the lateral decubitus position on the edge of the bed with the patient's back exposed to the caregiver carrying out the procedure; placing the patient in a fetal like knees to chest position with the head supported so that the head and spine are parallel to the bed; locating and identifying the injection site along the spine; anesthetizing the patient's skin in preparation for inserting an introducer and spinal needle; inserting the introducer at the marked puncture point; advancing the needle slowly through the introducer until the dura membrane is breached; visually and tactually verifying the orientation of side port as the needle is advanced using side port indicators; withdrawing the stylet disposed within the needle, after the dura membrane is pierced, as the needle is advanced; verify the presence of CSF flowing back through the needle hub by viewing CSF through the magnified window on the needle hub; visually and tactually verifying the orientation of side port for delivery of the drug; injecting the anesthetic through the needle to induce the anesthetic block; withdrawing the needle and introducer without replacing the stylet; and dressing the puncture site with a bandage.

[0063] The present invention may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrative and not restrictive. The scope of the invention is, therefore, indicated by the appended claims, rather than by the foregoing description. All changes which come within the meaning and range of equivalency of the claims are to be embraced within their scope.

What is claimed is:

1. A spinal needle comprising:

a needle hub with a hollow interior disposed about a proximate end of a hollow needle; and

a stylet cap disposed about a proximate end of a stylet, the stylet being capable of freely sliding inside the hollow needle and needle hub; and the stylet cap is capable of sliding into and creating a pressure fit with the needle hub that releasably secures the stylet cap to the needle hub and that is freely rotatable around its axis.

2. The spinal needle of claim 1, wherein the needle hub further comprises at least one side port indicator disposed about the needle hub, the side port indicator capable of providing visual and tactual verification by a user of the orientation of a side port on the needle.

3. The spinal needle of claim 1, wherein the needle hub further comprises a magnifying window disposed within the needle hub and providing a magnified view of the interior of the needle hub.

4. The spinal needle of claim further comprising an introducer hub disposed about a proximate end of a hollow introducer, the introducer hub having at least one bevel tip indicator disposed about the introducer hub, the bevel tip indicator capable of providing visual and tactual verification by a user of the orientation of bevel tip on the introducer.

5. A method for anesthesia comprising the steps of:

identifying an injection site along a patient's spine;

inserting the introducer at the injection site;

advancing a needle slowly through the introducer until a patient's dura membrane is breached;

visually and tactually verifying the orientation of a side port using side port indicators as the needle is advanced;

withdrawing a stylet disposed within the needle, after the dura membrane is pierced, as the needle is advanced;

verifying the presence of CSF flowing back through the needle by viewing CSF through a magnified window on a needle hub;

visually and tactually verifying the orientation of side port for delivery of a an anesthetic using side port indicators; and

injecting the anesthetic through the needle to induce an anesthetic block.

6. A spinal needle comprising:

an introducer hub disposed about a proximate end of a hollow introducer, the introducer hub having at least one bevel tip indicator disposed about the introducer hub and the bevel tip indicator capable of providing visual and tactual verification by a user of the orientation of a bevel tip on the introducer;

a needle hub disposed about a proximate end of a hollow needle capable of freely sliding inside the hollow introducer and introducer hub, the needle hub having at least one side port indicator disposed about the needle hub, the side port indicator capable of providing visual and tactual verification by a user of the orientation of a side port on the needle; and

a stylet cap disposed about a proximate end of a stylet, the stylet cap capable of forming a axially rotatable pressure fit with the needle hub, and the stylet being capable of freely sliding inside the hollow needle and needle hub.

7. The spinal needle of claim 6, wherein the needle hub further comprises a magnifying window disposed within the needle hub and providing magnified view of the interior of the needle hub.

* * * * *

US005116323A

United States Patent [19]

Kreuzer et al.

[11] Patent Number: 5,116,323

[45] Date of Patent: May 26, 1992

[54] **ARTERIAL CATHETER**

[75] Inventors: **James A. Kreuzer**, Bellbrook; **Min S. Lee**, Spring Valley, both of Ohio

[73] Assignee: **Becton, Dickinson and Company**, Franklin Lakes, N.J.

[21] Appl. No.: **644,067**

[22] Filed: **Jan. 22, 1991**

[51] **Int. Cl.**[5] **A61M 5/178**; A61M 25/01

[52] **U.S. Cl.** **604/164**; 604/280

[58] **Field of Search** 604/158-170, 604/280, 264, 171; 128/658, 772

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Primary Examiner—C. Fred Rosenbaum
Assistant Examiner—William Lewis
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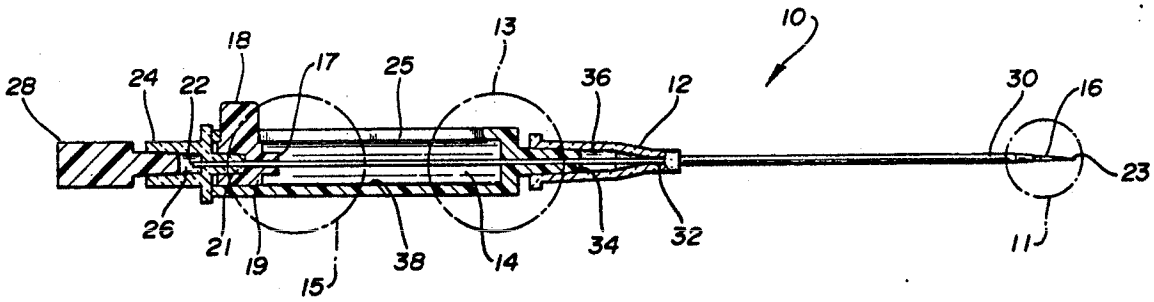
[57] **ABSTRACT**

An assembly is provided for easing the insertion and placement of an arterial catheter in the blood vessel of a patient. The assembly includes the combination of an insertion needle and guide tube which pass through the lumen of a catheter, and prior to use extends slightly out of the distal end of the catheter. The needle, in turn, extends slightly out of the distal end of the guide tube and serves to make the initial insertion through the skin and into the blood vessel. Once initial insertion is made, as indicated by blood "flash back" to the transparent needle hub, the guide tube is advanced through the catheter to provide a tracking path for the catheter. Once the distal end of the catheter has followed the guide tube path, the guide tube and needle are withdrawn. A feature of the invention is a guide tube slide arrangement for controlling the advance and retraction of the guide tube.

5 Claims, 1 Drawing Sheet



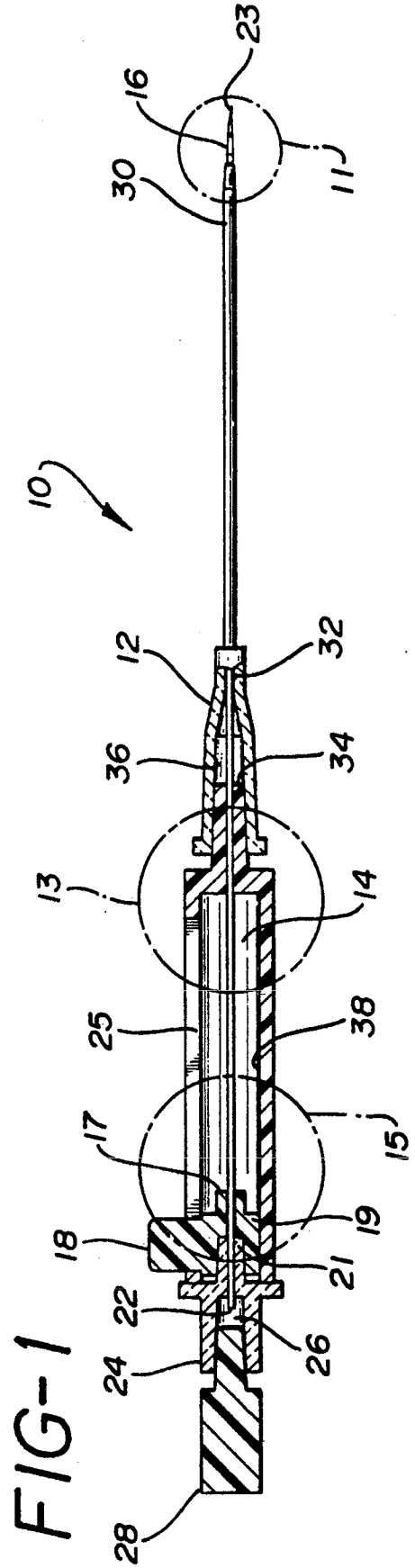


FIG-1

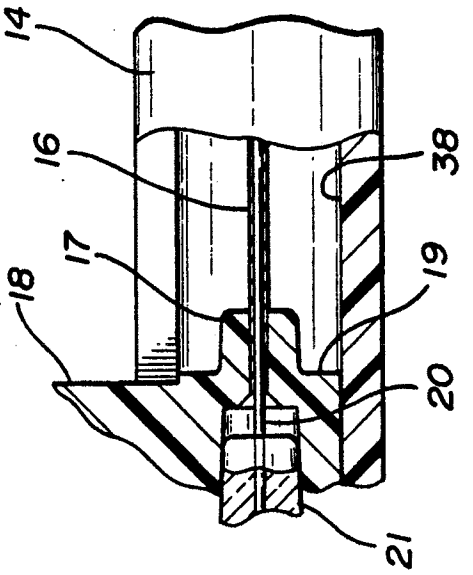


FIG-4

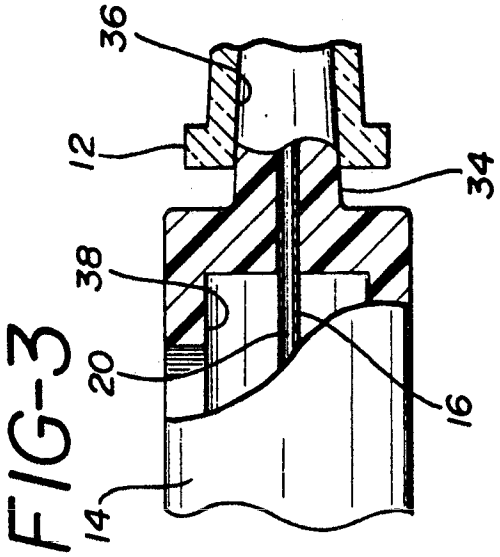


FIG-3

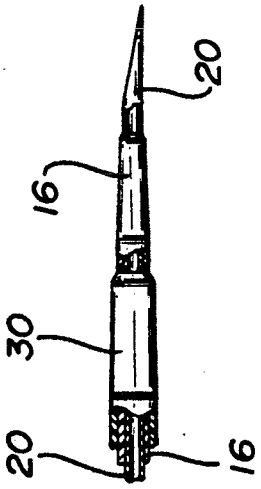


FIG-2

ARTERIAL CATHETER

BACKGROUND AND DESCRIPTION OF THE INVENTION

Generally speaking, this invention relates to an arterial catheter placement assembly. More particularly, this invention relates to such an assembly which provides ease of insertion and placement of the distal end of the catheter in the blood vessel of a patient in the desired location. That is, the assembly includes a combination needle and guide tube, both of which pass through the lumen of the catheter and extend slightly out the front end thereof prior to use. The assembly includes a guide tube slide mounted on the proximal end of the guide tube for controlling the advance and retraction of the guide tube in the assembly of the invention.

In the insertion and placement of a catheter, it is most important to ease as much as possible the movement through the skin of the patient and into the blood vessel. This is important not only from the standpoint of reducing the amount of pain entailed in such a procedure, but also in precise placement of the distal end of the catheter without any undue movement or experimentation.

In the past, placement assemblies of the kind discussed herein have included a guidewire which extends through the needle for providing a "track" for the movement of the catheter into its desired position in the blood vessel of a patient. Representative of such arrangements include, for example, U.S. Pat. No. 4,417,886 which teaches a catheter introduction set utilizing the combination of a needle and guidewire. In such an arrangement, the needle sharpened distal point is utilized to make an introduction through the skin of a patient and into the blood vessel thereof. Thereafter, the guidewire is moved forward through the blood vessel of the patient to the position where the distal end of the resulting catheter is desired. Then, the catheter is moved forward over the guidewire into the desired location. Once this takes place, the guidewire and needle are withdrawn. However, because of the flexibility of the guidewire itself, the actual positioning of the guidewire in the blood vessel may be somewhat tentative, simply because of lack of control of the movement of a wire.

With this invention by contrast, a combination needle and guide tube assembly are provided. That is, the needle and guide tube are positioned coaxially with the catheter and pass through the lumen thereof. The needle, in turn, passes through the lumen of the guide tube. In the initial positioning of the placement device of the invention here, the distal end of the needle extends slightly out of the distal end of the guide tube which in turn extends slightly out of the distal end of the catheter. Positioned on the rear end of the guide tube is a guide tube slide arrangement with a slide handle for manipulating the advancement and retraction of the guide tube.

Thus, the user inserts the needle through the skin of the patient and through the wall of the blood vessel under consideration. Thereafter, blood vessel entry is indicated in the transparent hub of the needle. Then, using the slide arrangement for the guide tube, the operator may advance the guide tube through the desired path in the blood vessel for providing a final path for positioning the distal end of the catheter. Subsequent to this controlled advancement of the guide tube, the catheter is advanced following the path initiated by the guide tube.

After this procedure has taken place, the guide tube and the needle may be withdrawn so that the catheter hub may be connected to appropriate equipment for blood draw, blood transfusion or the delivery of fluids or drugs.

As will be understood by practitioners-in-the-art, the entire circumferential extent of the catheter is guided by the guide tube path for insertion of the catheter to the precise location desired. Control is much more precise than is the case with use of a wire as a guide.

U.S. Pat. No. 3,825,001 teaches a catheter placement arrangement utilizing a guide tube. However, the guide tube assembly is locked in place on the proximal end hub of the catheter. There is no free manipulation of the guide tube to advance it forwardly and to withdraw it. It is simply removed from the hub of the catheter once placement has taken place.

With this invention, by contrast, the guide tube assembly with the slide control arrangement for placing the guide tube and withdrawing it includes a cooperating male luer lock connection which cooperates with the female luer lock connection of the catheter hub for ease of assembly and removal once placement has taken place. Nevertheless, the slide here provides guided advance for precise positioning of the catheter.

Other objects and advantages of this invention will be apparent from the following description, the accompanying drawings and the appended claims.

DESCRIPTION OF THE DRAWINGS

FIG. 1 is a longitudinal sectional view of a catheter placement assembly illustrating the invention;

FIG. 2 is an enlarged perspective view partially in section of a portion of the assembly of FIG. 1 as shown in the area defined by circle 11, and showing the cooperating positioning of the needle, the guide tube and the catheter of the assembly of the invention; and

FIG. 3 is an enlarged partially sectional view of a portion of FIG. I, defined by circle 13 and showing the connection in detail of the catheter hub with the guide tube slide body of the invention; and

FIG. 4 is an enlarged partially sectional view of a portion of FIG. 1, defined by circle 15 and showing the connection in detail of the guide tube slide body and the needle hub.

DETAILED DESCRIPTION OF THE INVENTION

Referring to the drawings, in which like reference characters refer to like parts throughout the several views thereof, FIG. 1 shows a catheter placement assembly generally designated 10 having a catheter hub 12 with a catheter 30 positioned in the front end opening 32 of catheter hub 12. Catheter hub 12 includes a female luer lock connection 36 tapered in the usual manner to receive the male luer lock connection 34 of a guide tube slide body 14.

The latter has a bore 38 therein for receiving in longitudinal sliding cooperating engagement a guide tube hub or slide body 19 controlled by a guide tube slide handle 18. Guide tube slide body 19 has a slot 25 for receiving handle 18 in sliding engagement. The guide tube slide body 19 includes a distal integral portion 17 for receiving therein a guide tube 16. Guide tube 16 passes through the catheter 30 and extends outwardly from the front end thereof as shown in FIG. 2. Again,

guide tube slide body **19** includes, in the proximal end thereof, a cooperating luer lock connection **21** providing cooperating tapered surfaces with the distal end of needle hub **24**.

Positioned in an integral forward extension **21** of needle hub **24** is a needle **20**, the proximal end **22** of which extends into chamber **26** of the transparent hub **24** for indicating "flash back" once blood has been passed through needle **20** from the point **23** thereof when **23** has passed into the blood vessel of a patient during a placement procedure.

As can be seen in FIGS. **1** and **2**, needle **20** extends through tube **16** and catheter **30** to extend outwardly a short distance from the guide tube **16**.

The assembly includes a plug **28** for plugging the proximal end of needle hub **24**. Plug **28** includes the usual air bleeding arrangement (not shown), as will be understood by practitioners-in-the art, to allow displacement of air from chamber **26** when blood moves rearwardly from point **23** to proximal end **22** of needle **20**.

Thus, in use, the assembly has the distal end thereof positioned substantially as shown in FIG. **2**. The technician inserts needle point **23** through the skin of a patient and into the blood vessel in question. Once insertion has been made and there has been flash back indication in chamber **26** through the transparent walls of needle hub **24**, the slide handle **18** may be grasped by the user to advance the guide tube **16** forwardly over the needle point and into the blood vessel. Then, the guide tube **16** is advanced to the desired location in the blood vessel.

Because the guide tube is passing through the lumen of the catheter and is in the form of a tube, it may be easily controlled to advance to the position desired. Once this has taken place, catheter **30** is advanced forwardly following the track of guide tube **16** into the desired position in the vessel. Guide tube **16** may be advanced through the use of the slide **19** and slide handle **18** to the desired position. Once positioning of the distal end of catheter **30** has taken place, guide tube **16** is withdrawn by use of handle **18** moving slide body **19** rearwardly through guide tube slide body **14**.

Thereafter, the needle, hub **24** and plug **20** together with the distal hub **34** of guide tube slide body **14** are withdrawn from the proximal end of catheter hub **12**, and appropriate equipment is connected to the placed catheter **30**, utilizing the female luer lock connection **36** of hub **12**.

As purely illustrative of materials which may be utilized for the guide tube of the invention, polyurethane formulations providing softening of the guide tube body upon exposure to blood is representative. One such formulation is Vialon®, a trademark of Becton, Dickinson and Company, designating a specific polyurethane formulation for that purpose. Of course, the same materials may be utilized for the catheter itself.

Thus, as will be appreciated from the above, there is provided in accordance with this invention a placement assembly for arterial catheters which provides a much more precise placement of the distal end of the catheter in the blood vessel of a patient. The slide arrangement provides much more precise control in advancement and withdrawal of the guide tube. Moreover, the fact that the guiding arrangement, in accordance herewith, is in fact, a tube, the entire circumferential extent of the catheter wall is appropriately guided during the entire guiding path provided by the guide tube of the invention.

While the forms of apparatus herein described constitute preferred embodiments of the invention, it is to be understood that the invention is not limited to these precise forms of apparatus, and that changes may be made therein without departing from the scope of the invention which is defined in the appended claims.

What is claimed is:

1. A catheter placement assembly, comprising

(a) a catheter having a distal end, a proximal end, and a lumen extending from said distal end to said proximal end;

(b) a catheter hub positioned on the proximal end of said catheter;

(c) a catheter placement tube extending coaxially through said catheter lumen;

(d) said catheter placement tube having a distal end, a proximal end and a lumen extending from said distal end to said proximal end;

(e) a catheter tube slide body positioned on said catheter placement tube adjacent the said proximal end of said catheter placement tube;

(f) a catheter tube slide positioned on said proximal end of said catheter placement tube;

(g) said catheter tube slide mounted for relative reciprocable movement in said catheter tube slide body;

(h) a catheter placement tube hub positioned on said distal end of said catheter tube slide body for detachable connection to said catheter hub;

(i) an insertion needle extending coaxially through said catheter placement tube lumen;

(j) said insertion needle having a sharpened distal end extending outwardly from said distal end of said catheter placement tube, and a lumen extending from said distal end to the proximal end thereof;

(k) a transparent hollow needle hub positioned on said proximal end of said insertion needle for detachable connection to said catheter tube slide; and

(l) means in said transparent needle hub for venting air therefrom when the said distal end of said needle makes vein entry;

(m) whereby when vein entry has been made, said needle hub is removed from said catheter tube slide body, said needle is removed from said catheter placement tube lumen and said catheter tube slide is moved forward distally through said catheter lumen to provide a guide path for said catheter distal end.

2. The catheter placement assembly of claim **1**, wherein

(a) said detachable connection between said catheter tube slide body and said catheter hub is a luer lock connection.

3. The catheter placement assembly of claim **1**, wherein

(a) said detachable connection between said needle hub and catheter hub slide is a luer lock connection.

4. The catheter placement assembly of claim **1**, wherein

(a) said catheter tube slide body has an elongated slot;

(b) a handle on said catheter tube slide;

(c) said handle extending through said slot for moving said catheter tube slide along said catheter tube slide body.

5. The catheter placement assembly of claim **1**, wherein

(a) said catheter and said catheter placement tube are comprised of a material which softens when exposed to blood.

* * * * *

US005250035A

United States Patent [19]

Smith et al.

[11] Patent Number: 5,250,035

[45] Date of Patent: Oct. 5, 1993

[54] CANNULA AND STYLET SYSTEM

[75] Inventors: Gary N. Smith, Libertyville; Donald H. Patrick, Gurnee, both of Ill.

[73] Assignee: Abbott Laboratories, Abbott Park, Ill.

[21] Appl. No.: 871,559

[22] Filed: Apr. 20, 1992

[51] Int. Cl.[5] A61M 5/178

[52] U.S. Cl. 604/164; 604/168; 604/900

[58] Field of Search 604/491, 51, 53, 158, 604/164, 165, 166, 168, 170, 174, 274, 900; 606/185; 128/753, 754

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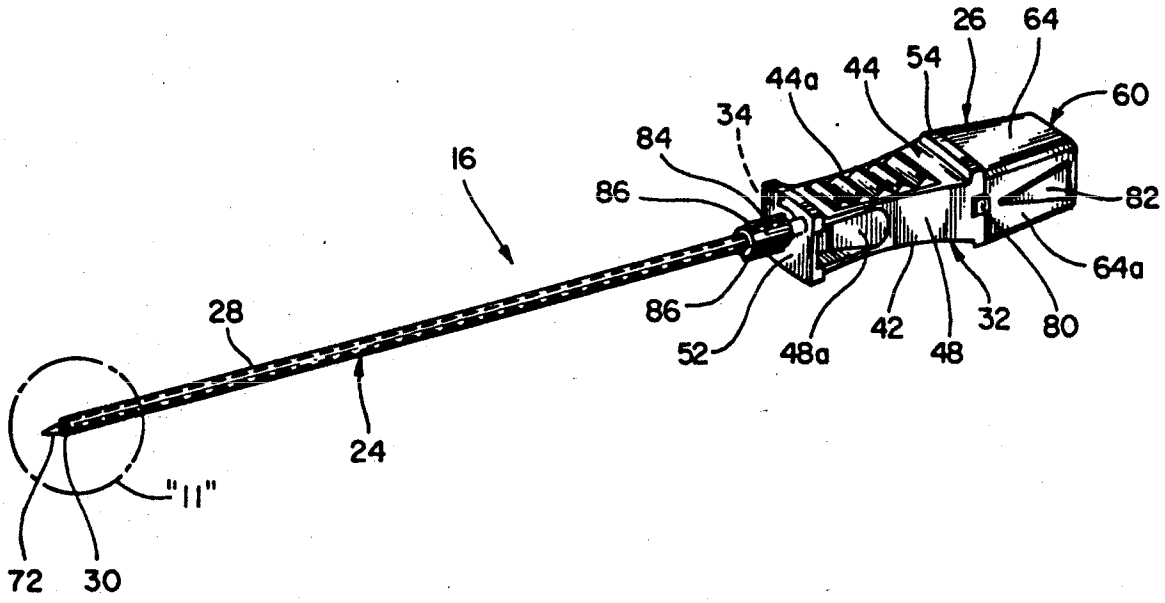
Primary Examiner—John D. Yasko
Assistant Examiner—Anthony Gutowski
Attorney, Agent, or Firm—Thomas M. Breininger

[57] ABSTRACT

A needle system including a plastic cannula and a stylet, and a procedure utilizing the needle system for positioning the end of a spinal catheter within the subarachnoid space surrounding a patient's spinal cord for continuous administration of anesthetics and/or analgesic medications. The stylet has a pencil-point sharpened end for forming a minimal size opening in the dura defining the subarachnoid space to minimize the loss of cerebrospinal fluid therefrom during this procedure. The cannula has a hub formed of glass-clear plastic, which is provided with viewing recesses.

2 Claims, 3 Drawing Sheets



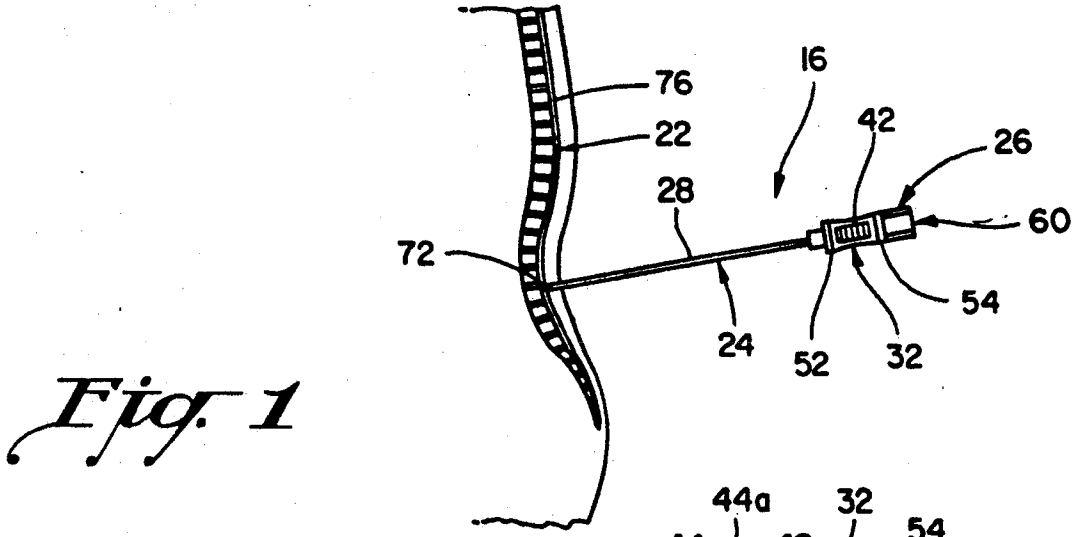


Fig. 1

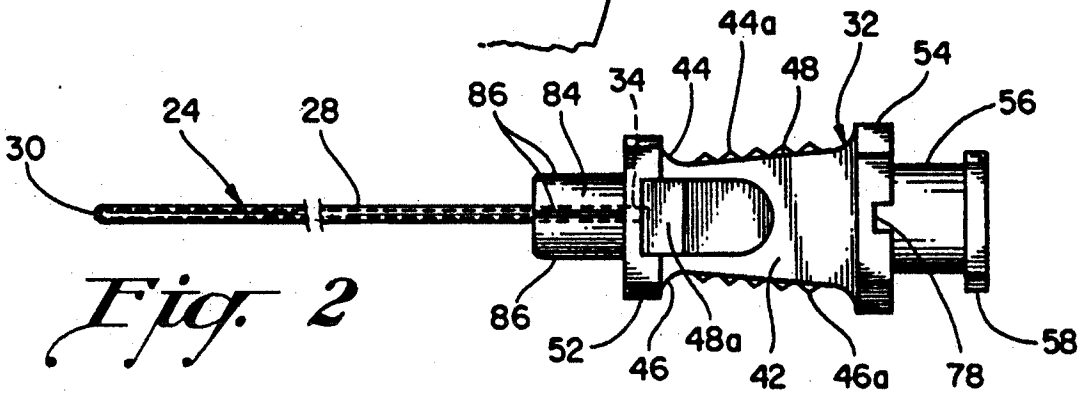


Fig. 2

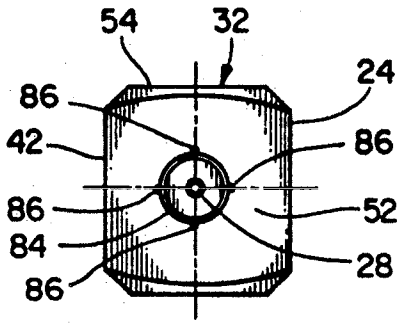


Fig. 3

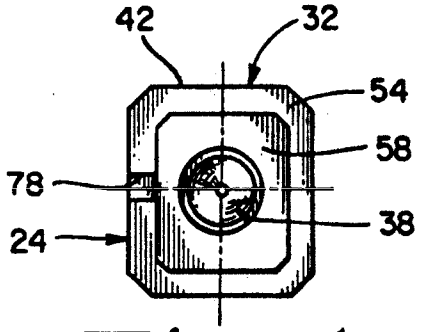


Fig. 4

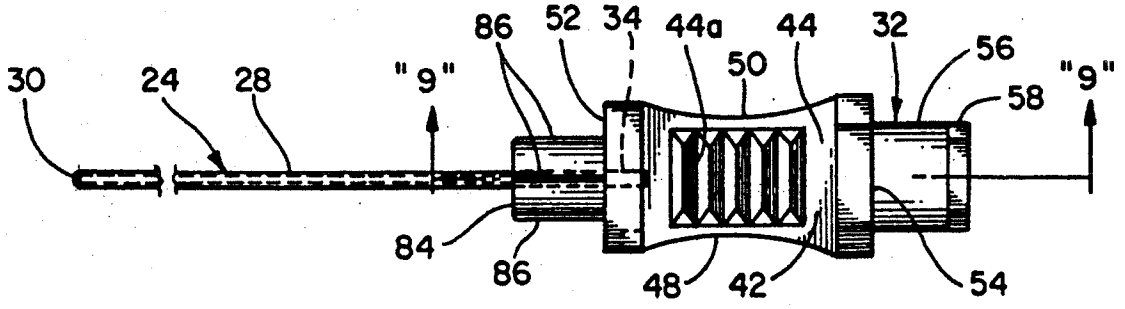


Fig. 5

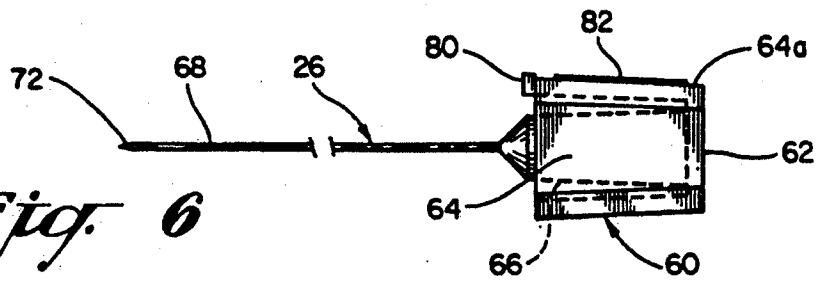


Fig. 6

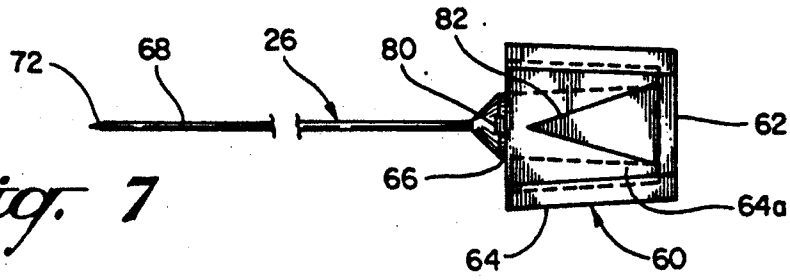


Fig. 7

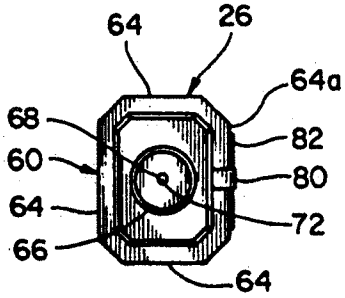


Fig. 8

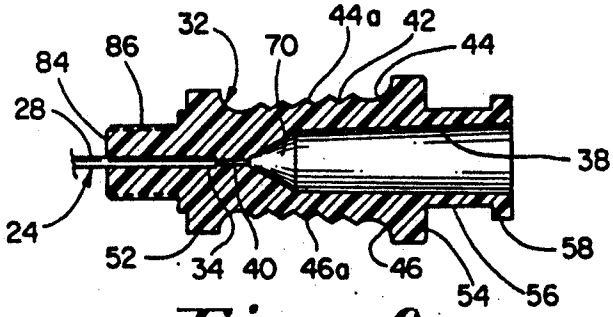


Fig. 9

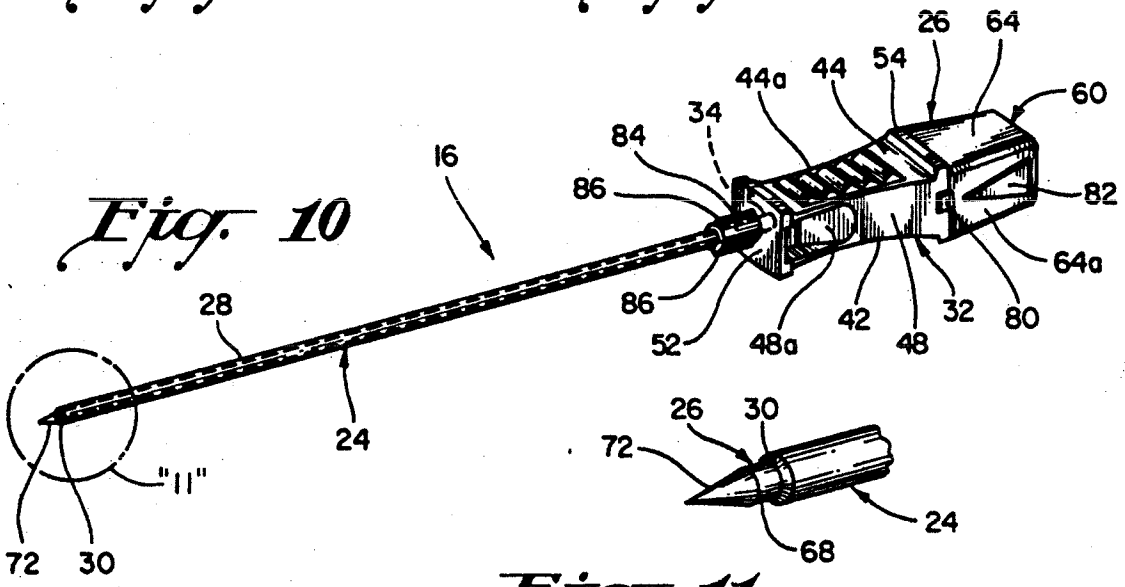


Fig. 10

Fig. 11

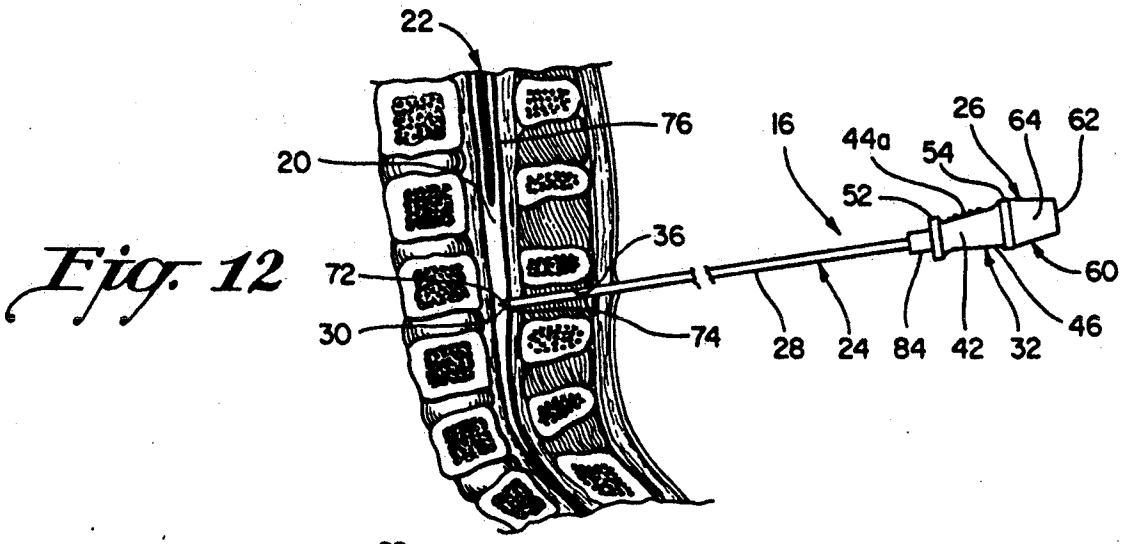


Fig. 12

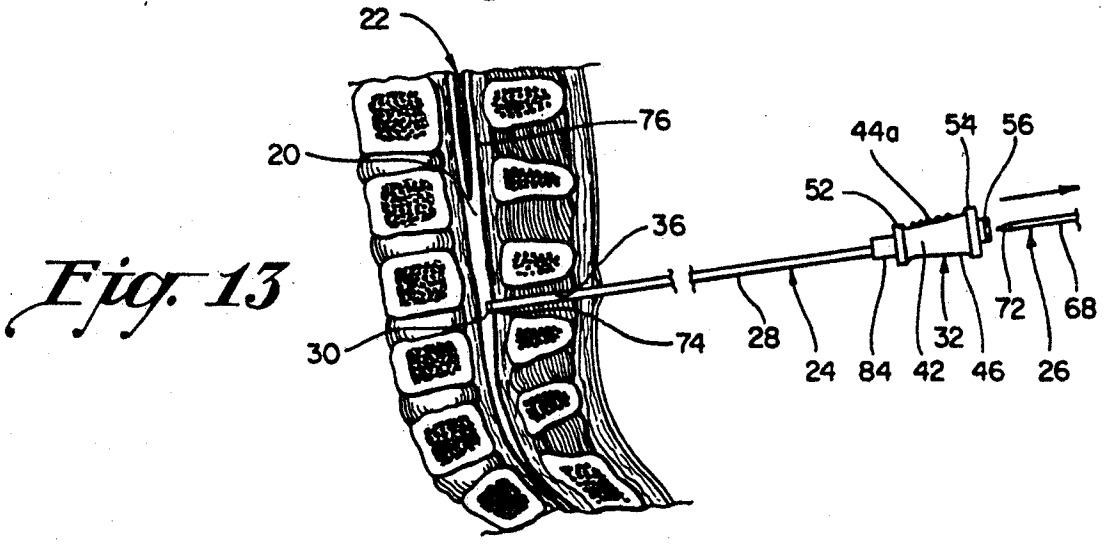


Fig. 13

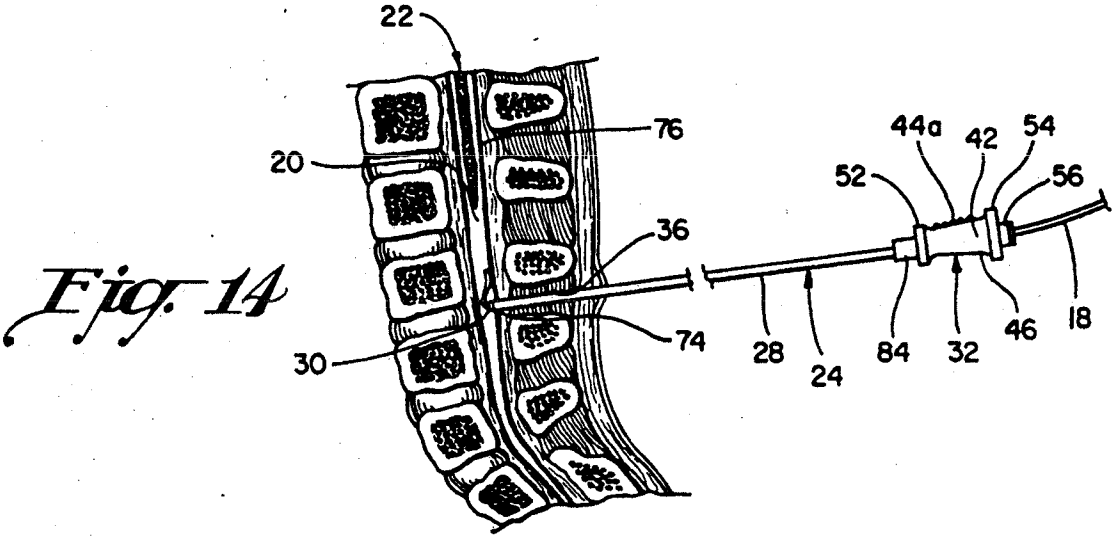


Fig. 14

CANNULA AND STYLET SYSTEM

BACKGROUND OF THE INVENTION

Administering anesthetics and/or analgesic medications into the spinal canal through the dura of the spinal cord has to be done very carefully so as to minimize the loss of cerebrospinal fluid from the subarachnoid space which surrounds the spinal cord through such administration openings made in the dura. The loss of the cerebrospinal fluid produces such extremely severe spinal headaches in patients having this anesthetic procedure that, in certain cases, the patient must be maintained in a horizontal position so as to endure same. When such anesthetics, etc. are administered by means of spinal needles it may be necessary for multiple punctures to be made in a patient's dura which obviously increases the likelihood of a further loss of cerebrospinal fluid with each puncture. Further, such spinal needles quite commonly have a chisel-shaped point whereby the fibers of the dura are severed during the puncture procedure which requires a healing period before the puncture wound is fully closed to seal off the escape of further cerebrospinal fluid.

SUMMARY OF THE INVENTION

The present invention is directed to a new and improved needle system and procedure by means of which a spinal catheter may be introduced into the subarachnoid space surrounding the spinal cord with a minimal loss of cerebrospinal fluid through the dura. With this arrangement, anesthetics and/or analgesic medications may be administered to a patient at intervals as desired without the necessity of making separate punctures through the dura each time.

This needle system is characterized by a cannula, preferably formed of a plastic such as Teflon, which has a non-pointed but beveled distal end and a clear-plastic hub on its proximal end, the hub being provided with a through bore which is axially aligned with the bore of the cannula. The needle system of the present invention is further characterized by a stainless steel stylet which is insertable into the cannula and which has a plastic handle on its proximal end which interfits with the hub of the cannula so that, when so assembled, just a dura-piercing tip or point at the distal end of the stylet projects beyond the non-pointed distal end of the cannula. It is noted that the dura-piercing tip of the stylet is cone-shaped or pencil-point shaped whereby in piercing the dura the fibers thereof are gently spread apart rather than severed, as with chisel-shaped points, whereby to minimize the size and trauma of the opening therein. Further, this type of puncture wound heals much faster than one in which the tissue fibers have been severed. After a minimal size opening has been made in the dura with just the tips of the stylet and the cannula extending therethrough into the subarachnoid space surrounding the spinal cord, the stylet is removed from the cannula and a spinal catheter is passed therethrough into the subarachnoid space, after which the cannula is removed and the spinal catheter anchored down.

The present invention is directed to a new and improved needle system and procedure for administering anesthetics or analgesics to a patient in a manner such that there is a minimal loss of cerebrospinal fluid and thus a lessening of extremely painful spinal headaches.

An object of the present invention is to provide such a new and improved needle system which is characterized by a plastic cannula having a beveled distal end with a bored hub on its proximal end and a stainless steel stylet having a cone-shaped or pencil-point distal end and a handle on its proximal end which is engageable with the cannula hub when the stylet is inserted therein so that only the pencil-point distal end projects beyond the beveled end of the cannula whereby a minimal size opening is formed in the dura of the spinal cord whereby a spinal catheter may be introduced into the subarachnoid space surrounding the spinal cord upon removal of the stylet from the cannula.

A further object of the present invention is to provide such a new and improved needle system wherein the interengageable means between the cannula and the stylet is a notch provided in the cannula hub and a tab provided on the stylet handle.

Additional objects and advantages of the present invention will become apparent to one skilled in the art from the following detailed description.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a diagrammatic view of a patient's back and spinal column and applicants' new and improved needle system for administering anesthetics and/or analgesics to the patient;

FIG. **2** is a front elevational view of the cannula of applicants' new and improved needle system shown in FIG. **1**;

FIG. **3** is a left end elevational view of the cannula shown in FIG. **2**;

FIG. **4** is a right end elevational view of the cannula shown in FIG. **2**;

FIG. **5** is a top plan view of the cannula shown in FIG. **2**;

FIG. **6** is a top plan view of the stylet of applicants' new and improved needle system shown in FIG. **1**;

FIG. **7** is a front elevational view of the stylet shown in FIG. **6**;

FIG. **8** is a left end elevational view of the stylet as shown in FIG. **7**;

FIG. **9** is a longitudinal sectional view taken generally along line **9—9** of FIG. **5**;

FIG. **10** is a perspective view of a preferred embodiment of applicants' new and improved needle system;

FIG. **11** is an enlarged partial perspective view of the distal ends of the assembled cannula and stylet of applicants' needle system, the enlarged portion being circled with broken line in FIG. **10**;

FIG. **12** is a diagrammatic view illustrating the use of applicants' new and improved needle system in forming a catheter opening in a patient's dura;

FIG. **13** is a diagrammatic view of the next step in applicants' new and improved procedure during which the stylet is withdrawn from the cannula after formation of the opening in the patient's dura; and

FIG. **14** is a diagrammatic view of the next step in applicants' new and improved procedure during which the distal end of a spinal catheter is introduced into the patient's subarachnoid space through the cannula which extends through the opening formed in the patient's dura, the cannula being removable from the patient after the above-described proper positioning of the spinal catheter, after which removal the spinal catheter may be suitably anchored to the patient and an appropriate drug delivery system assembled to the proximal end thereof.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring now to the drawings, a preferred embodiment of a new and improved needle system **16** of the invention is shown in FIGS. **2–11** with a preferred embodiment of a new and improved procedure of the invention for introducing a spinal catheter **18** into a subarachnoid space **20** which surrounds a patient's spinal cord **22**, utilizing the new and improved needle system **16**, being shown in FIGS. **1** and **12–14**.

As best illustrated in FIG. **10**, the needle system **16** has a cannula **24** and a stylet **26** which are interfitted together when the procedure of the invention is initiated (FIGS. **1** and **12**). The cannula **24**, which is shown separately in FIGS. **2–5** and **9**, is characterized by an elongated tubular member **28** having a non-pointed but beveled distal end **30** with a hub **32** provided on the opposite proximal end **34** thereof. Preferably, the elongated member **28** is formed of a smooth, inert thermoplastic, such as Teflon, which has a greater self-lubricating property than a material, such as steel, upon insertion of the elongated member **28** into a previously formed elongated puncture-like epidural passage **36** formed in a patient's back by a known-type introducer (not shown) and terminating adjacent a dura **76** which surrounds the patient's spinal cord **22** at a position along the length thereof where it has been determined by medical experts that placement of the spinal catheter **18** therethrough would be most effective for continuous administration of anesthetics and/or analgesic medications prior to and/or during and/or after various procedures. The hub **32**, which is preferably formed of a plastic which is as nearly "glass-clear" as possible for a purpose which will be discussed hereinafter, is provided with a luer-tapered bore **38** (FIG. **9**) which is axially aligned and in fluid communication with the proximal end **34** of the elongated member **28** mounted in the hub **32** through an axial passage **40** extending therebetween. The hub **32** is characterized by a gripping portion **42** having upper and lower curved surfaces **44** and **46**, respectively, provided with transverse ridges **44***a* and **46***a* for gripping purposes and having front and rear curved surfaces **48** and **50**, respectively, with viewing-window depressions **48***a* and **50***a* provided adjacent both the proximal hub-mounted end **34** of the elongated member **28** and the axial passage **40**, the purpose for which will be discussed hereinafter. The gripping portion **42** has a generally rectangular flange formation **52** at its end adjacent the cannula **24** and a generally rectangular flange formation **54** at its opposite end. Projecting coaxially from the flange formation **54** is a sleeve member **56** which defines an extension of the luer-tapered bore **38** in the hub **32** and which has a generally rectangular flange **58** provided on the end thereof for a purpose which will be discussed hereinafter.

The stylet **26**, as illustrated in FIGS. **6,7,8,10** and **11**, is characterized by a generally rectangular, open-topped box-like handle **60** which is preferably molded of plastic. As viewed in FIGS. **6,7** and **10**, the handle **60** is shown on its side with its open top facing toward the left. The handle **60** is characterized by a bottom wall **62** and four side walls **64**, all of which flare slightly outwardly from the bottom wall **62**. A generally cylindrical post **66** is formed integrally on the inner surface of the bottom wall **62**, in centered relationship thereon, and extends outwardly thereof beyond the edges of the side walls **64** and has a relatively stiff length of thin stylet wire **68** axially mounted, at its proximal end, in the post **66**. The post **66** is provided with a luer-taper whereby when the stylet **26** is inserted into or assembled to the cannula **24**, the stylet wire **68** passes into the bore **38** of the hub **32**, through the axial passage **40**, and into the proximal end **34** of the cannula **24** with the luer-taper post **66** being tightly received within the luer-tapered bore **38**. The sleeve **56**, during the foregoing assembly, enters the annular space defined between the post **66** and the side walls **64** with the fit being such that the outer end surface of the flange **58** engages the inner surface of the bottom wall **62** of the handle **60** and the outer edges of the side walls **64** engage the outer end surface of the flange formation **54**, to stabilize the assembly thereof. The diameter of the stylet wire **68** is such that it freely passes through the axial passage **40** in the hub **32** and through the bore of the cannula **24**. Preferably the inner end of the bore **38** is funnel-shaped, as at **70** in FIG. **9**, to facilitate insertion of the stylet **26** into the cannula **24**. The relative lengths of the stylet **26** and the cannula **24** is such that when fully assembled, as described, only a distal pointed end **72** of the stylet wire **68** extends just slightly beyond the beveled distal end **30** of the cannula **24**, as best illustrated in FIGS. **10** and **11**. The stylet pointed end **72**, as best shown in FIG. **11**, is provided with a pencil-point or cone-shaped configuration to minimize the size of a spinal catheter opening **74** (FIG. **13**) made in a patient's dura **76** and thus minimize the loss of cerebrospinal fluid from the subarachnoid space **20**, the less fluid lost the less severe the spinal headache suffered by the patient. It is noted that preferably the beveled distal end of the cannula **24** is formed to blend smoothly with the pointed end **72** of the stylet **26**.

With reference to FIGS. **2,4, 6–8**, and **10**, interengageable means may be provided on the cannula hub **32** and the stylet handle **60**. A notch **78** (FIGS. **2** and **4**) may be provided on the hub flange **54** with a complementary tab (FIGS. **6,7,8** and **10**) being formed on the leading edge of one of the side walls **64***a* of the stylet handle **60**. The notch **78** and tab **80** are preferably configured to provide a known-type detent action therebetween for retaining the cannula **24** and stylet **26** in fully assembled relationship until such time that it is desired to withdraw the stylet **26** from the cannula. The handle sidewall **64***a* may have a raised arrow **82** molded thereon which points to the tab **80**.

A secondary hub **84** having circumferentially spaced longitudinally disposed gripping ribs **86** is preferably provided on the cannula end of the hub **32** (FIGS. **2,3,5,9** and **10**) for receiving the open end of a plastic needle guard (not shown).

The new and improved procedure for placing the distal end of the spinal catheter **18** through the dura **76** and into the subarachnoid space **20** with a minimal loss of cerebrospinal fluid and thus a minimization of the severity of spinal headaches suffered by patients permits the continuous or selectively spaced administration of anesthetics and/or analgesic medications without multiple intrusions through the dura **76**. After an initial passage or puncture has been made by a known-type introducer, the new and improved needle system **16**, comprising the stylet **26** assembled in the smooth, plastic cannula **24**, is inserted into the initially formed passage with the pencil-point end **72** of the stylet **26** and the beveled end **30** of the cannula **24** forming a minimal size opening **74** in the dura **76** (FIG. **12**) by spreading apart the fiber of the dura **76** rather than severing same, as

occurs when stylets having wedge-shaped pointed ends are used for this purpose. It is noted that the dura openings **74** formed primarily by applicants' pencil-point stylet **26** tend to heal more rapidly than those formed by such wedge-shaped pointed ends.

After the dura opening **74** has been formed by the needle assembly **16**, the stylet **26** is removed from the cannula **24** (FIG. **13**), after which confirmation that the subarachnoid space **20** has been reached may be accomplished by aspirating spinal fluid through the cannula **24**, the viewing recesses or depressions **48***a* in the cannula hub **32** permitting a visual indication and confirmation of the presence of spinal fluid in the axial passage **40** of the cannula hub **32**, same being formed of a "glass-clear" plastic. Then, the spinal catheter **18** is inserted through the cannula **24** which is still disposed in the dura opening **74** and into the subarachnoid space **20** (FIG. **14**). The cannula **24** may then be removed from the patient and the spinal catheter **18** anchored to the patient in a suitable manner.

Preferably the stylet **26** and the spinal catheter **18** should be of the smallest diameter possible, such as a 22 gauge stylet needle and a 24 gauge spinal catheter. Further, the spinal catheter **18** should fit as snugly as possible in the dura opening **74** so as to minimize the leakage of spinal fluid therepast.

While there has been shown and described preferred embodiments of the needle system and the procedure of the invention, it will be obvious to those skilled in the art that changes and modifications may be made without departing from the invention, and it is intended by the appended claims to cover all such changes and modifications as fall within the same spirit and scope of this invention.

We claim:

1. A needle system for introducing a spinal catheter into the subarachnoid space surrounding a spinal cord with a minimal loss of cerebrospinal fluid, said system comprising, a plastic cannula having a centrally bored hub provided at one end thereof, an elongated stylet having a cone-shaped pencil-point end and a handle at its opposite end, which stylet is insertable into said cannula through said hub, the relative lengths of said cannula and said stylet being such that, when said stylet handle abuts against said cannula hub upon full assembly thereof, said pencil-point end of said stylet projects beyond the end of said cannula whereby a minimal opening is formed in the dura by said pencil-point end of said stylet to minimize the loss of cerebrospinal fluid therethrough during removal of said stylet and insertion of a spinal catheter into the subarachnoid space through said cannula wherein said stylet is formed of stainless steel, and said cannula hub is formed of glass-clear plastic and is provided with indicator means.

2. A needle system for introducing a spinal catheter into the subarachnoid space surrounding a spinal cord with a minimal loss of cerebrospinal fluid, said system comprising, a non-pointed but beveled cannula having a hub provided at one end thereof, a bore extending through said hub in axial alignment with a bore of said cannula, an elongated stylet having a cone-shaped pointed end and a handle at its opposite end, which stylet is insertable into said cannula through said hub, the relative lengths of said cannula and said stylet being such that, when said stylet handle abuts against said cannula hub upon full assembly thereof, said cone-shaped pointed end of said stylet projects beyond the end of said non-pointed but beveled cannula whereby, when said fully assembled cannula and stylet are inserted into a previously formed elongated puncture in a patient's back, said cone-shaped pointed end of said stylet and said beveled end of said cannula pierce the dura just enough to form a minimal opening into the subarachnoid space within the dura, whereupon removal of said stylet from said cannula permits introduction of a spinal catheter through said cannula and into said subarachnoid space with a minimal loss of cerebrospinal fluid therefrom wherein said stylet is formed of stainless steel, said handle is formed of plastic, said hub is formed of glass-clear plastic and is provided with one or more viewing-window depressions.

* * * * *

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(54) TRANSITION SECTION FOR A CATHETER

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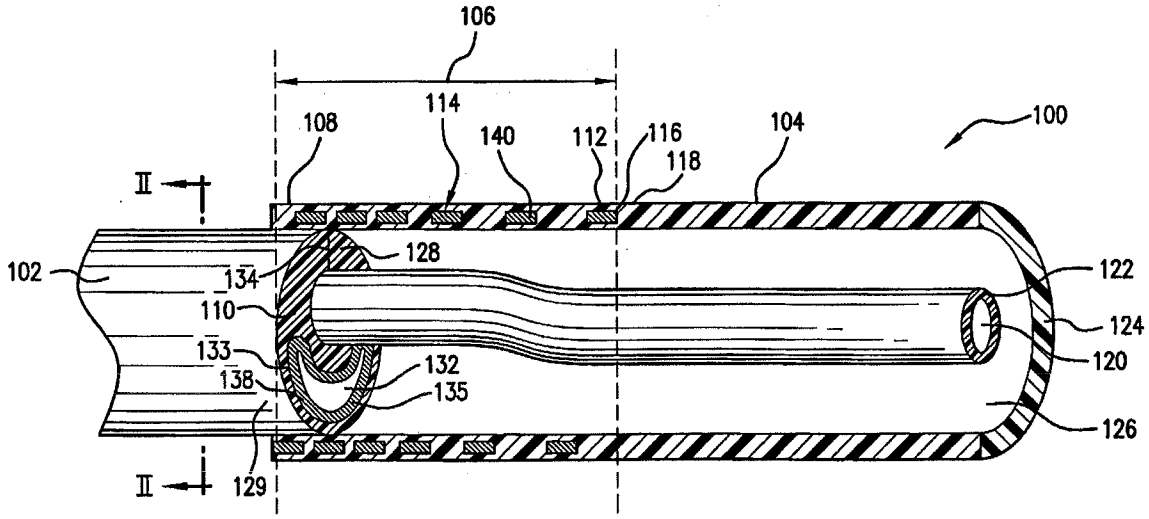
(52) U.S. Cl. 604/525

(57) ABSTRACT

A catheter having a proximal shaft defining a guidewire lumen and an inflation lumen. The inflation lumen is arcuate shaped and reinforced with a tube having an arcuate shaped cross-section or another reinforcing means. The catheter also has a distal shaft, with a greater flexibility than the proximal shaft. The catheter also has a transition section. A proximal end of the transition section communicates with the proximal shaft, and a distal end communicating with the distal shaft. The transition section has a gradually increased flexibility from its proximal end to its distal end. The transition section includes a transition means creating the increased flexibility.



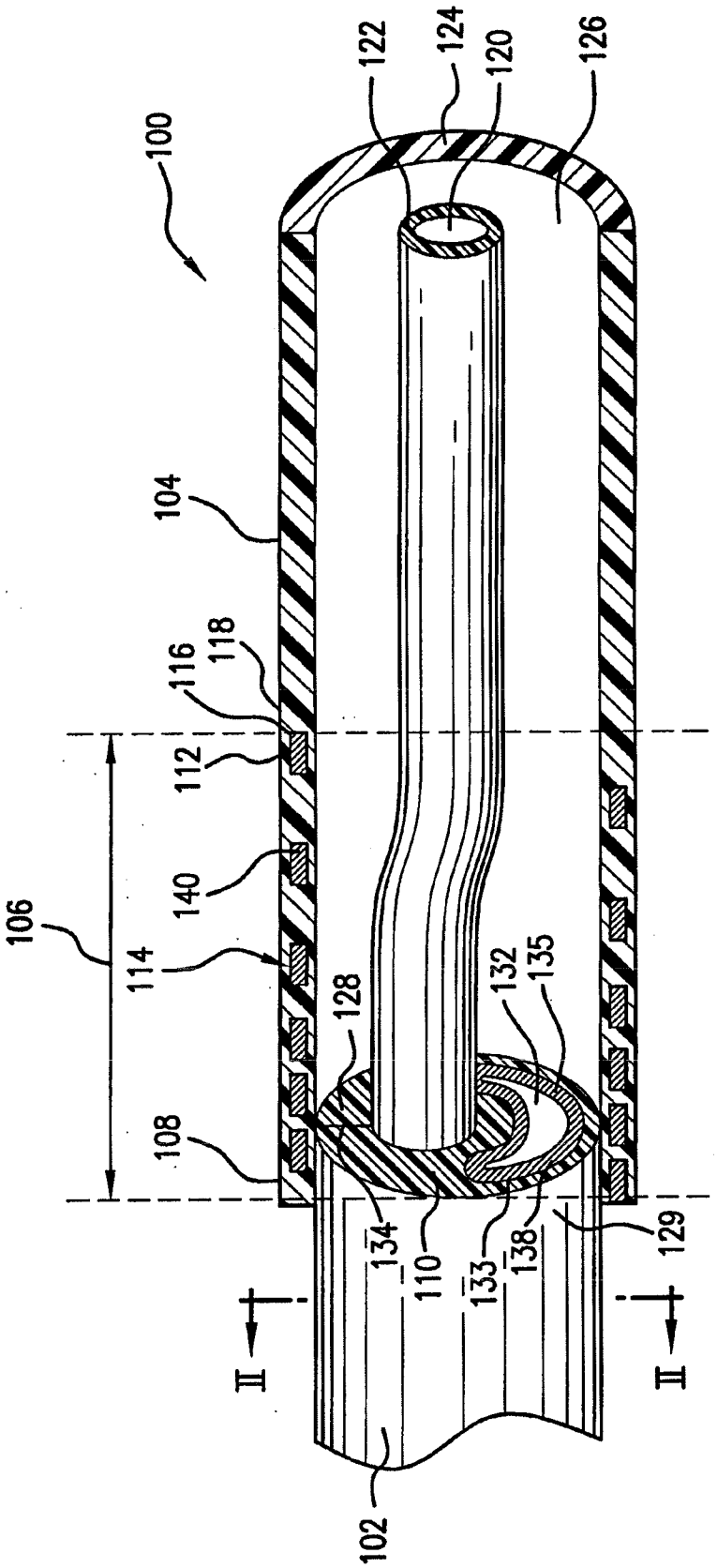

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FIG. 1

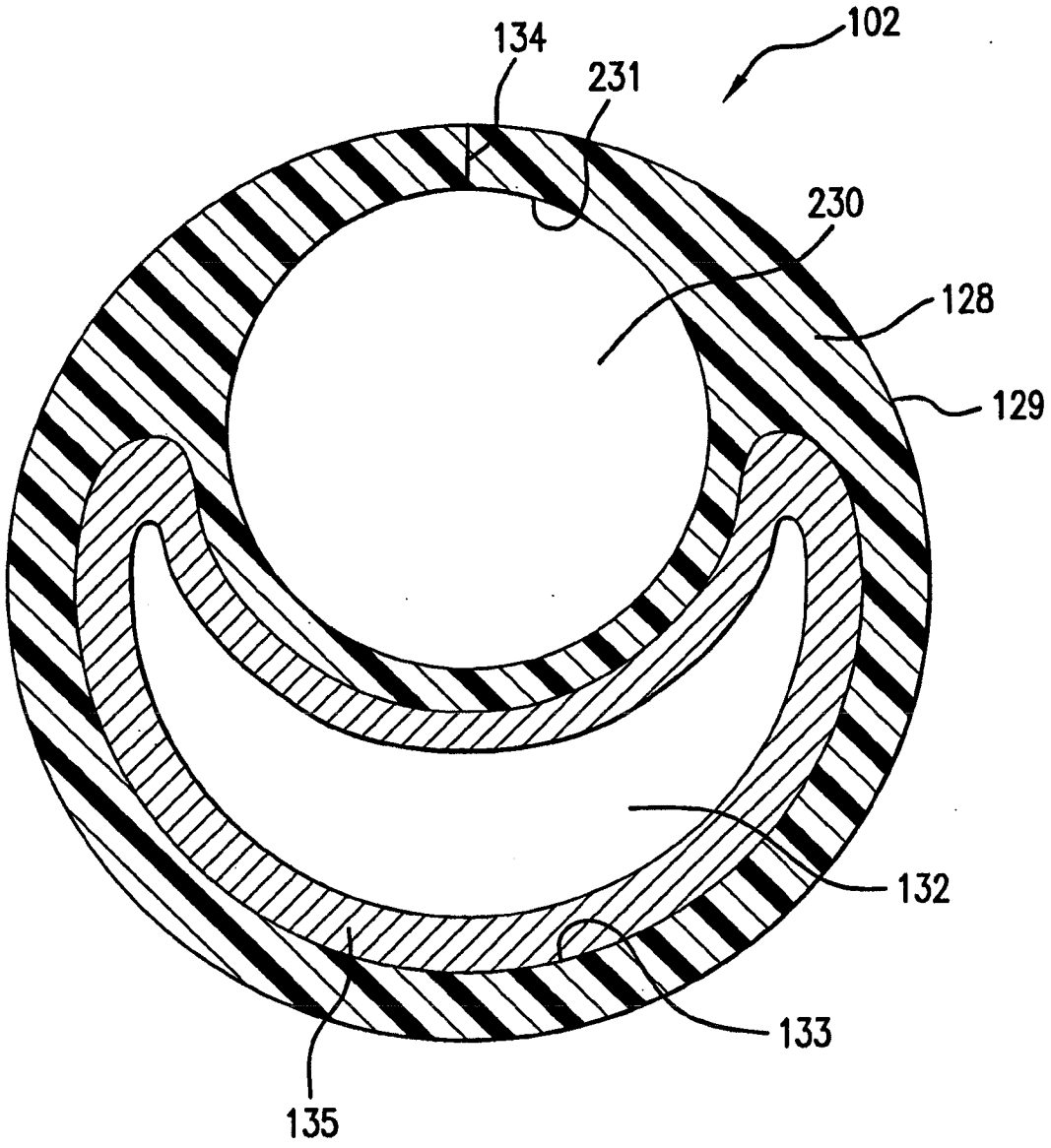

FIG. 2

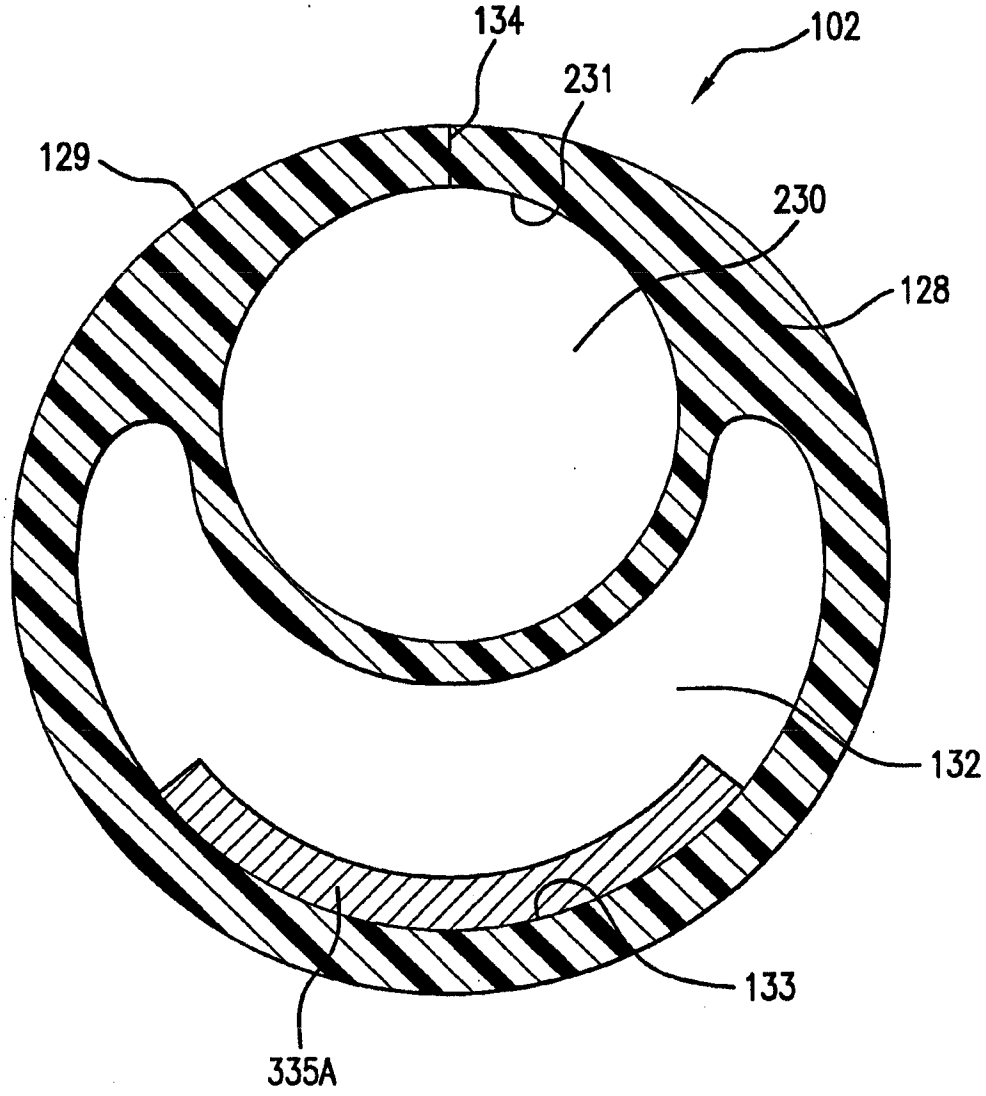

FIG.3A

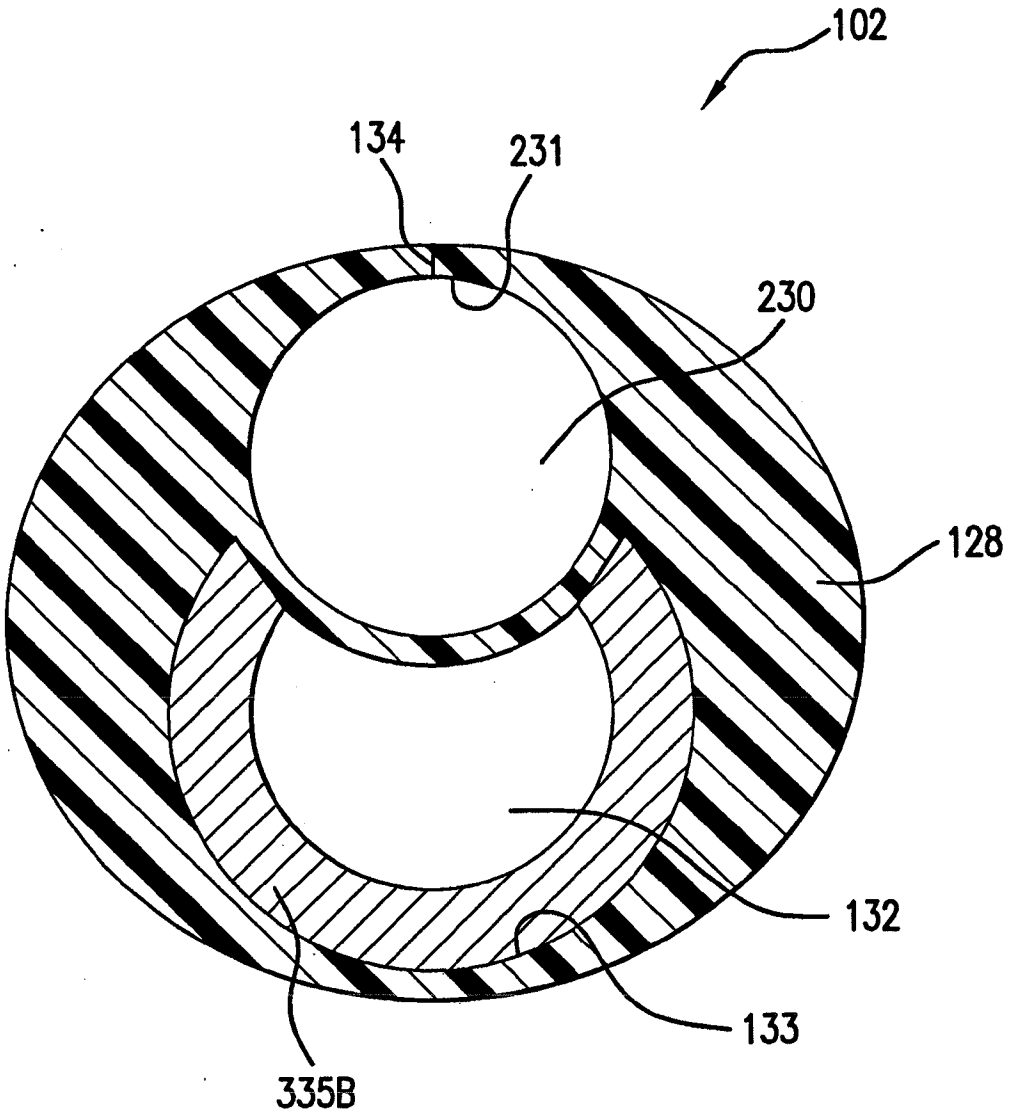

FIG.3B

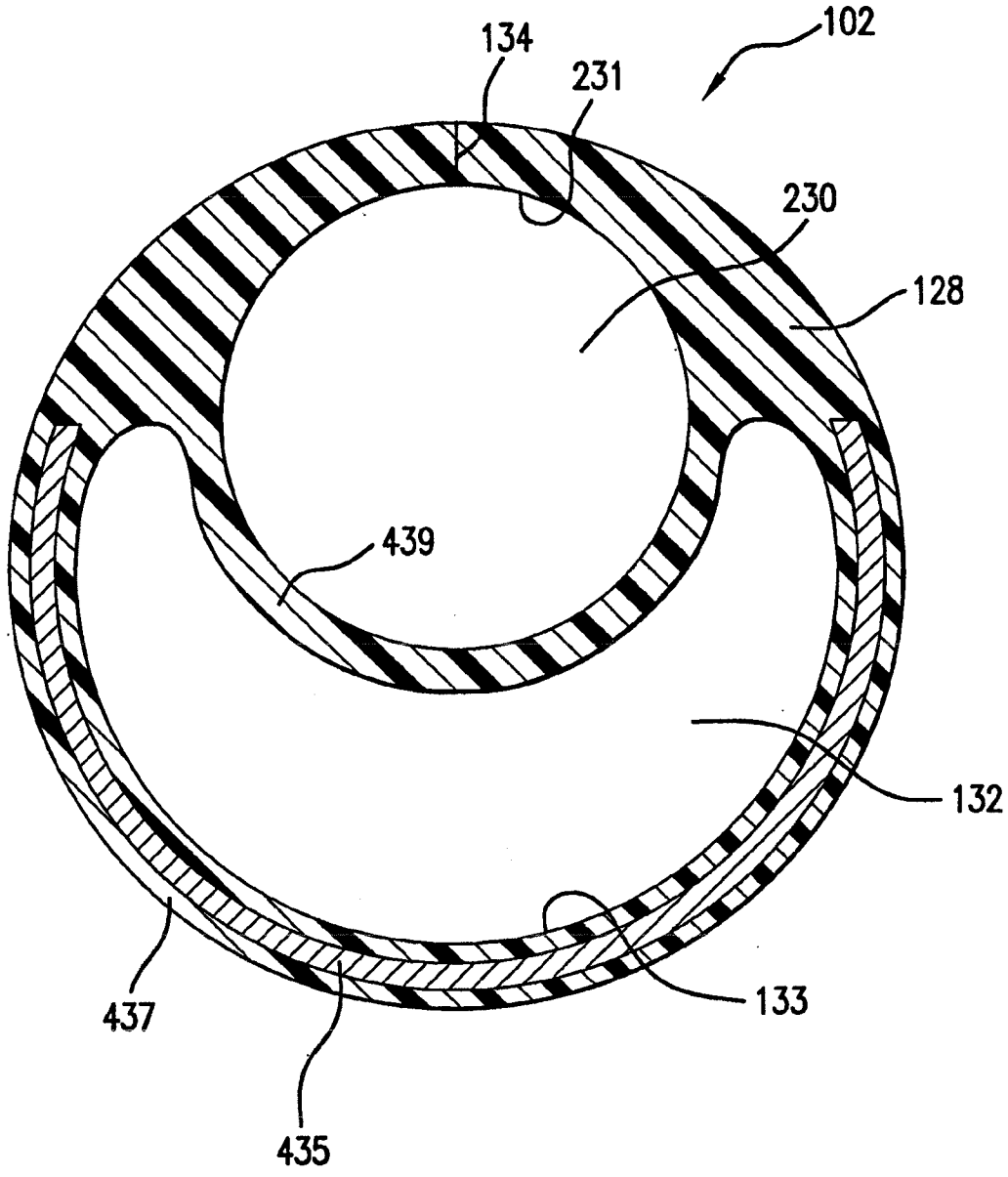

FIG.4A

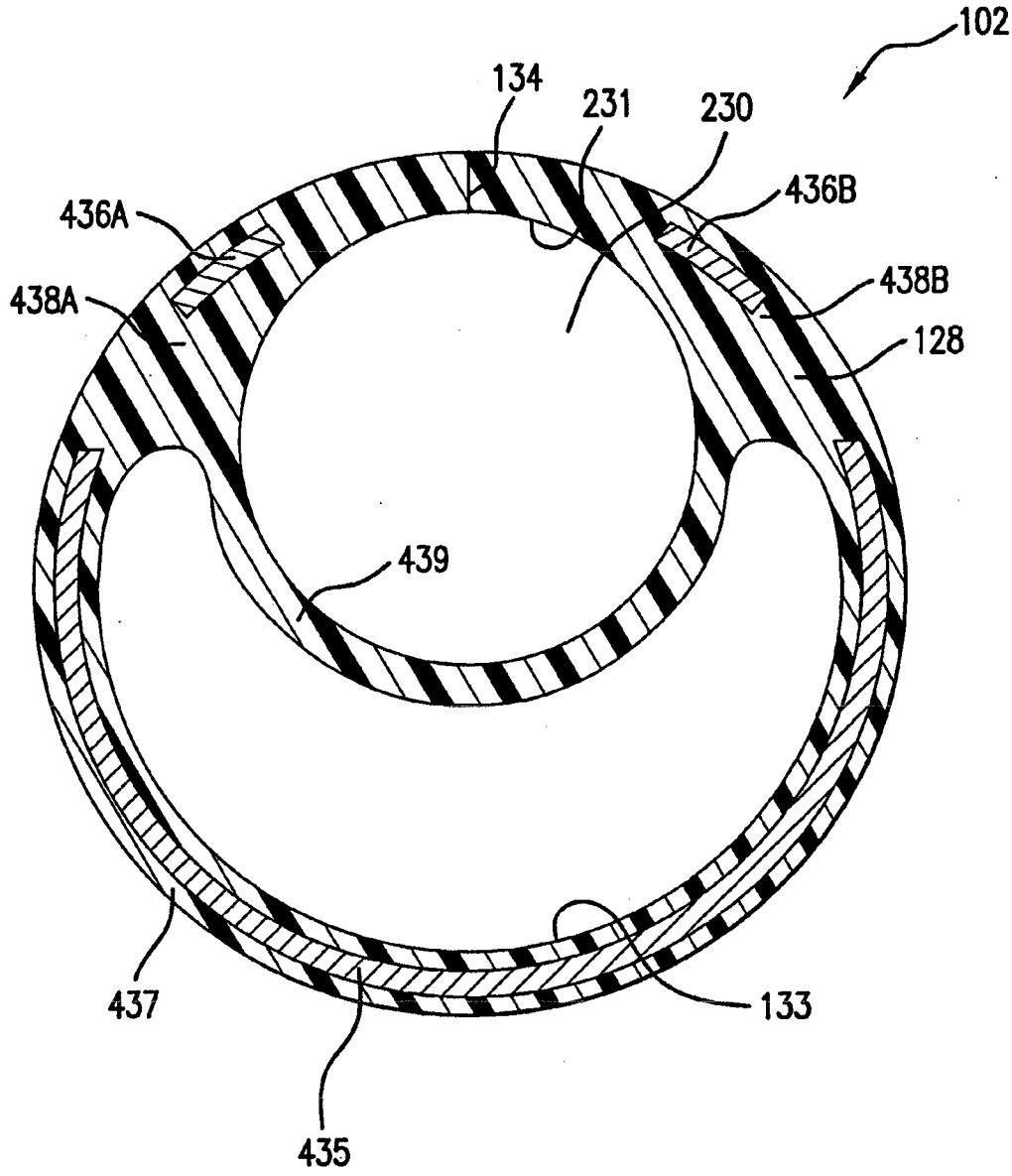

FIG.4B

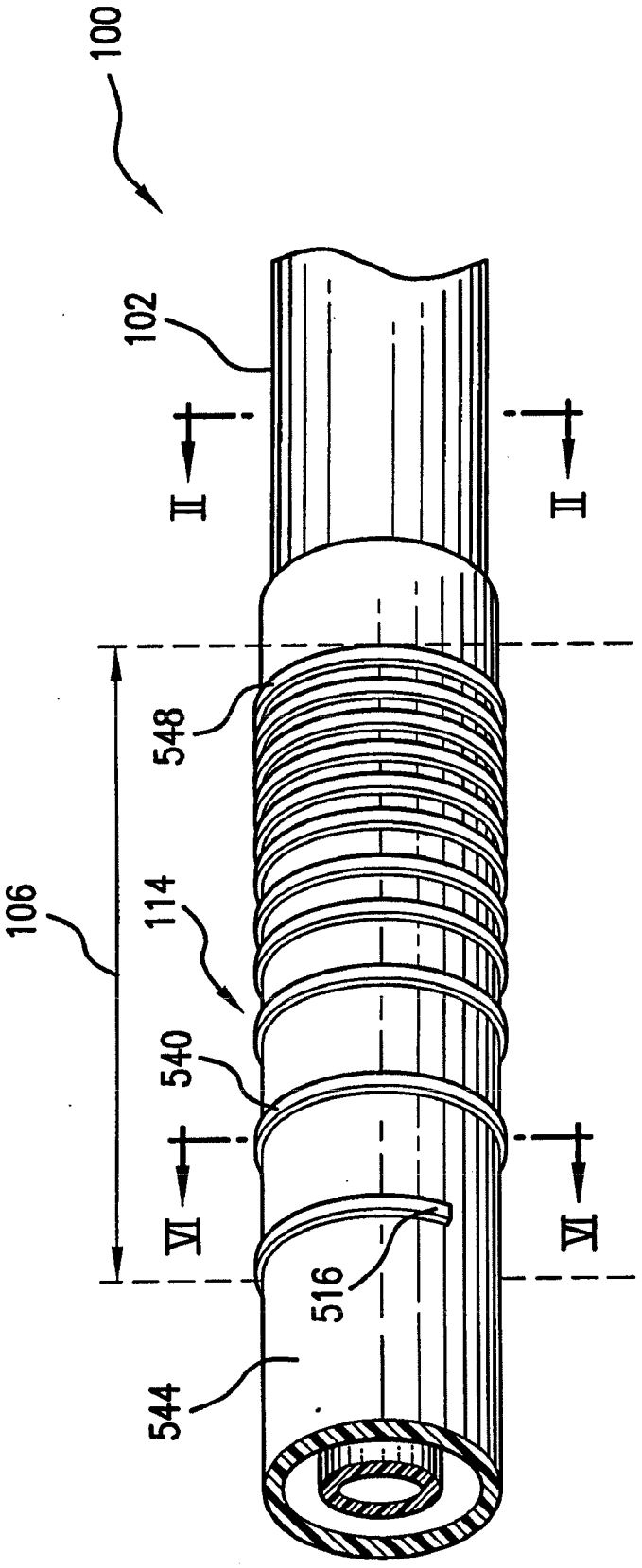

FIG.5

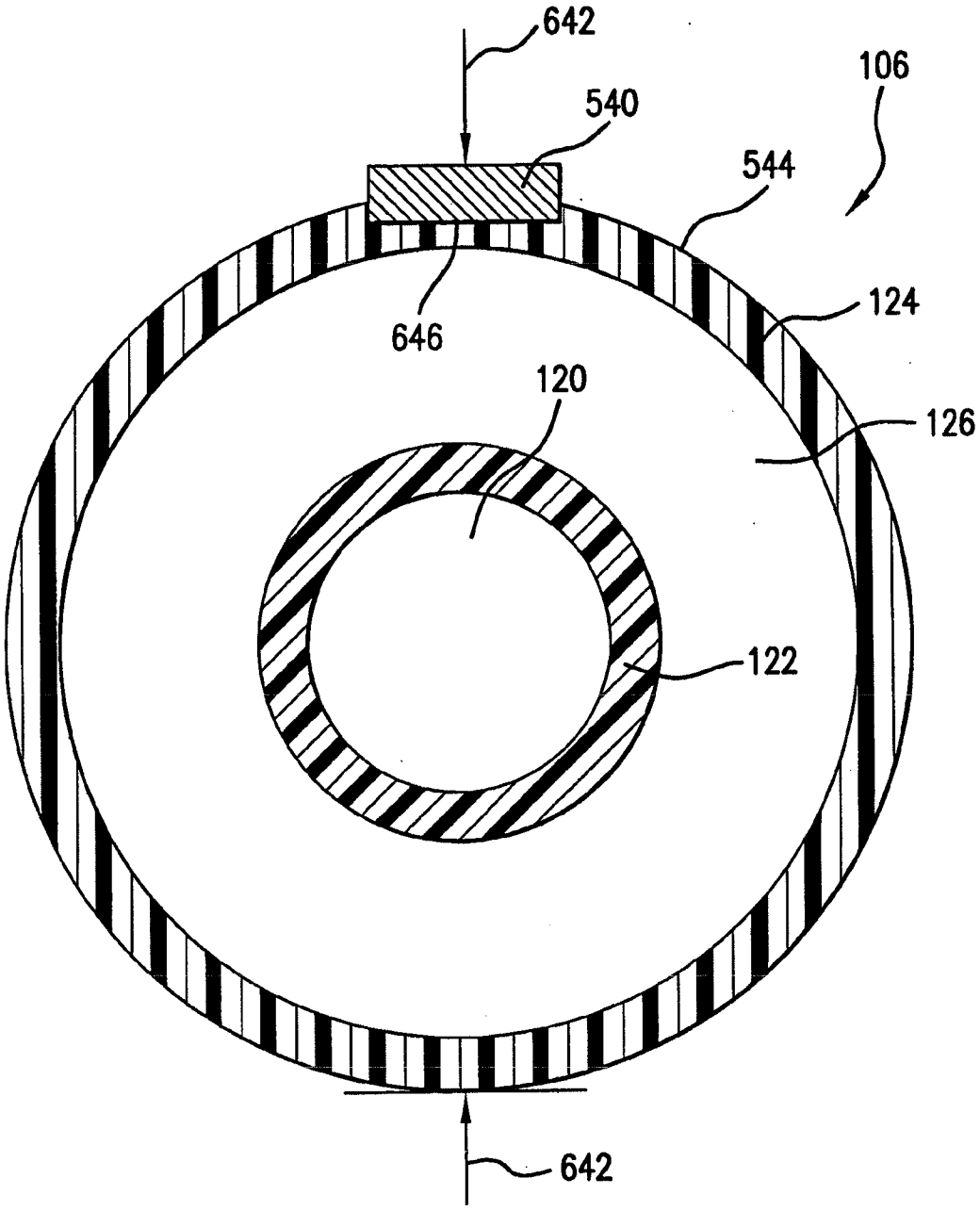

FIG.6

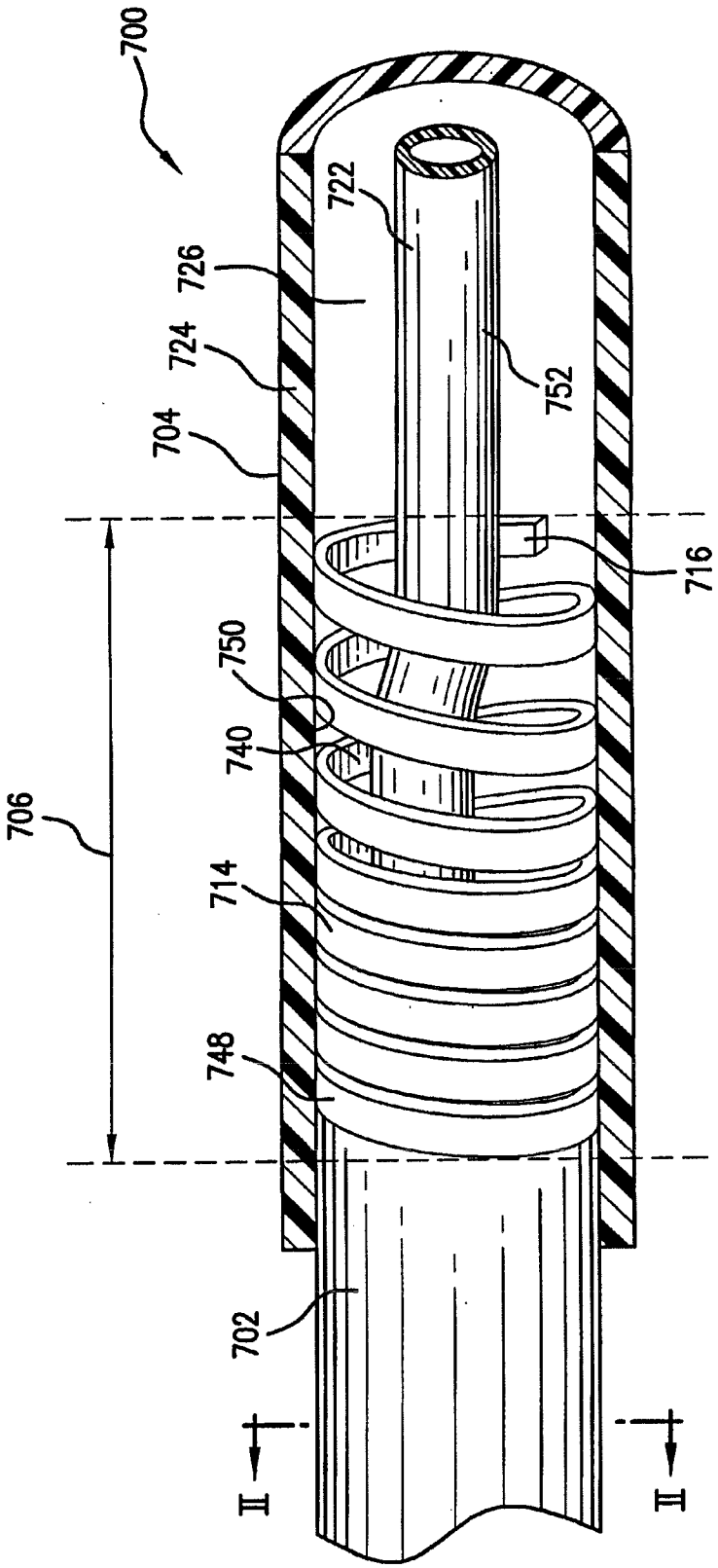

FIG. 7

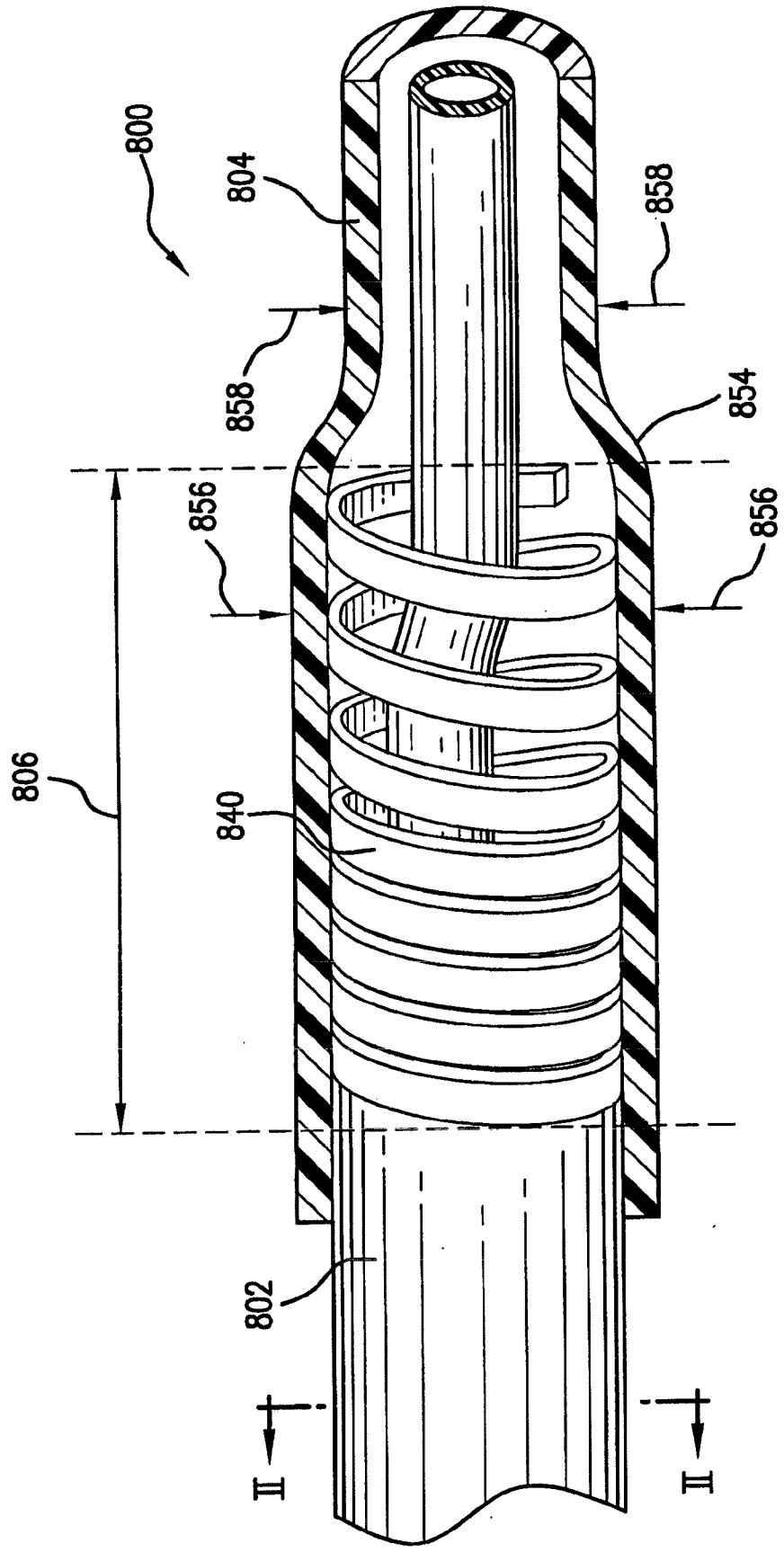

FIG. 8

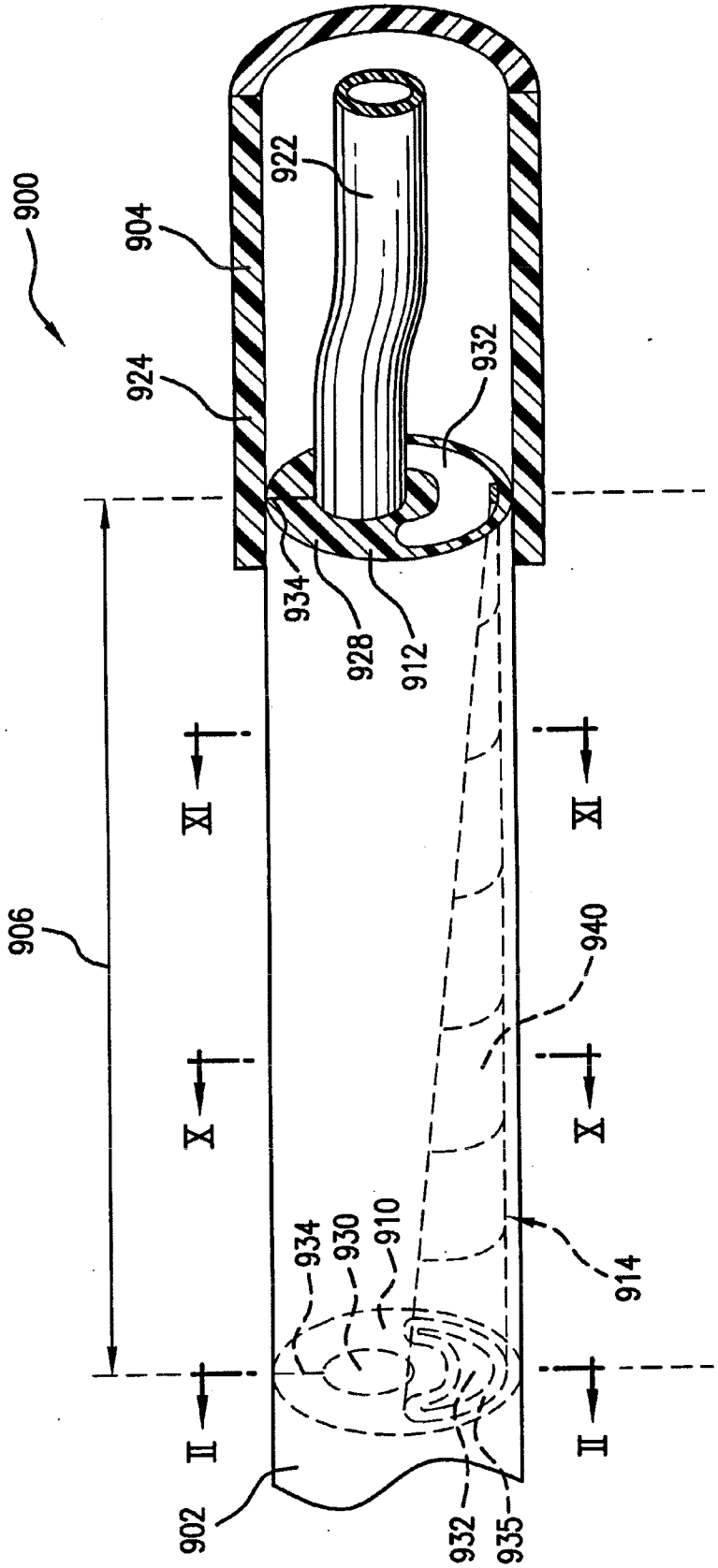
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FIG.9

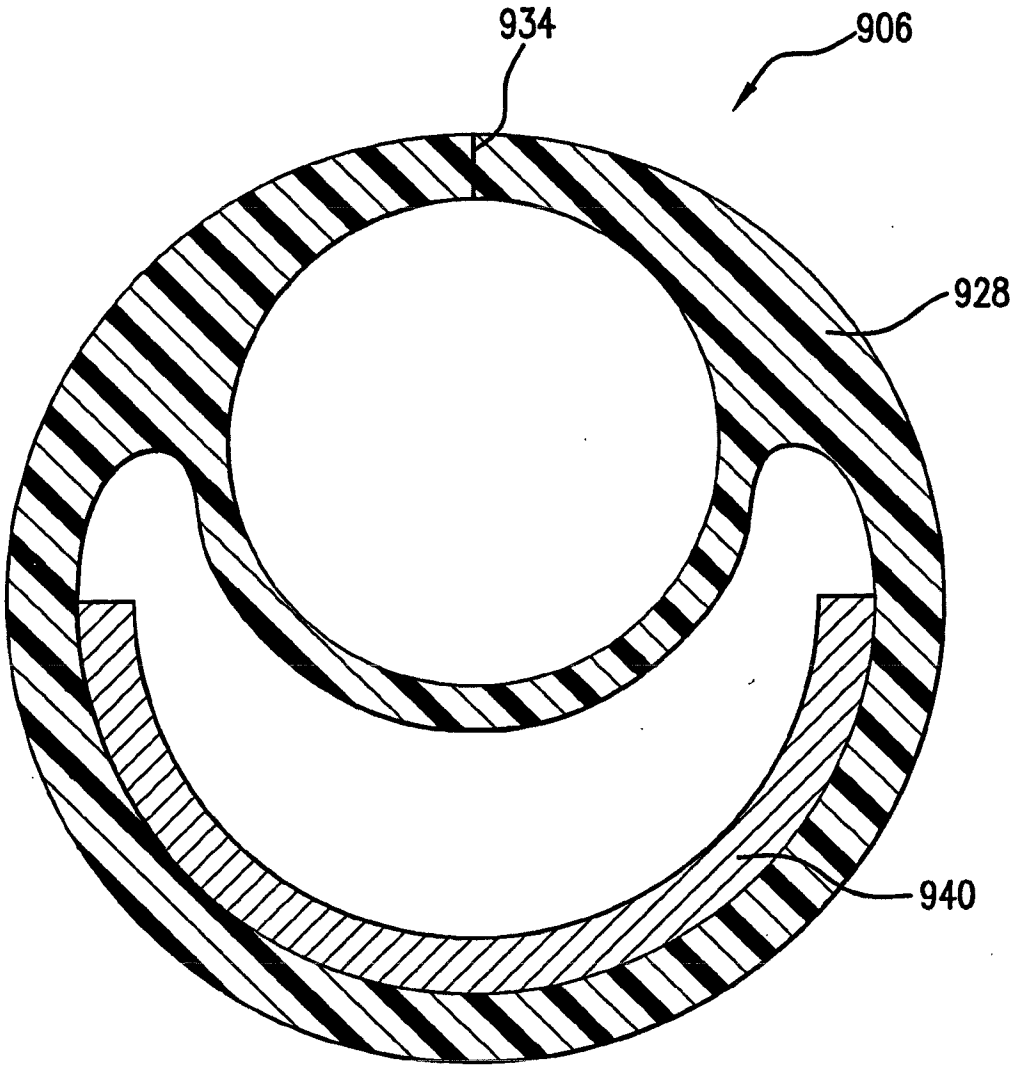

FIG. 10

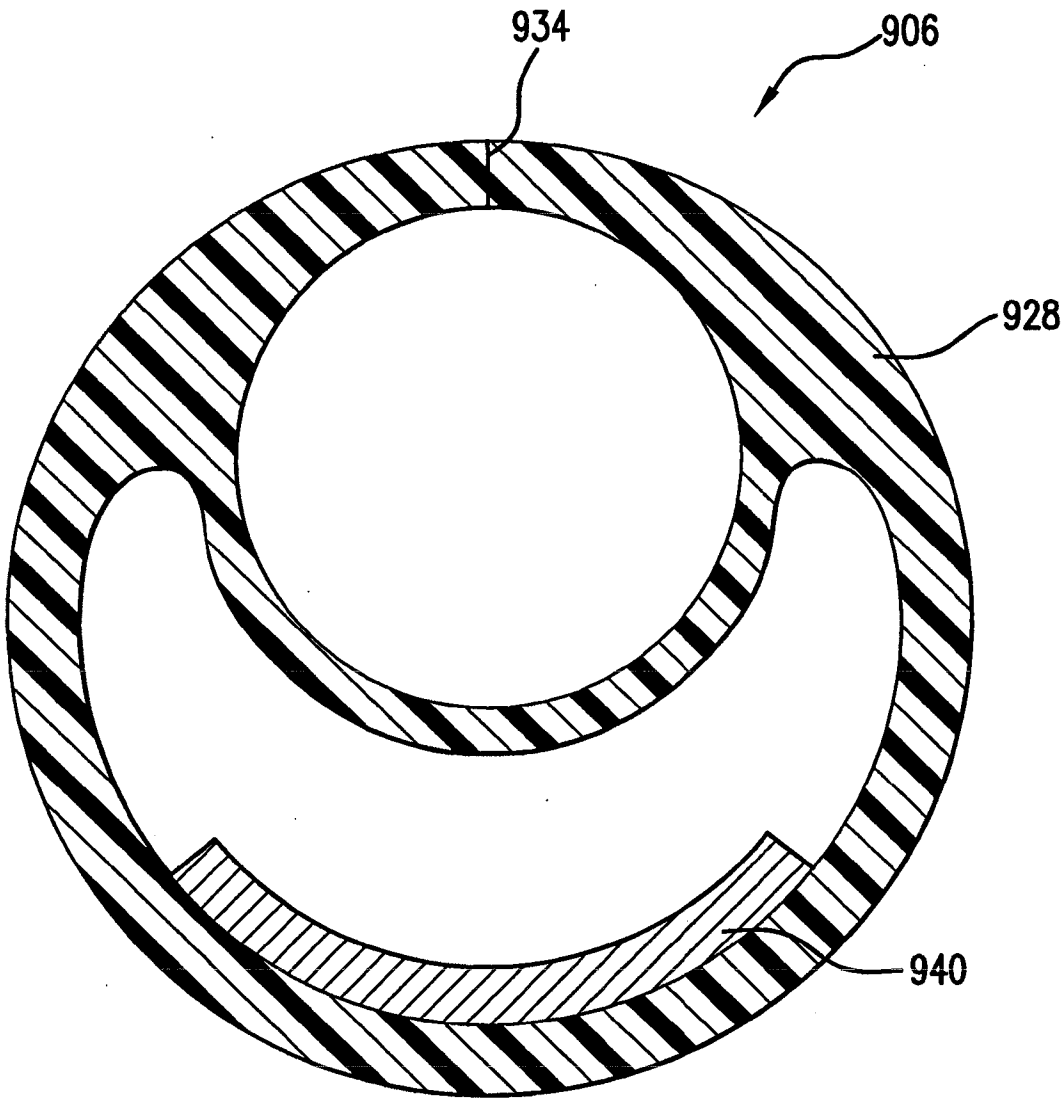

FIG. 11

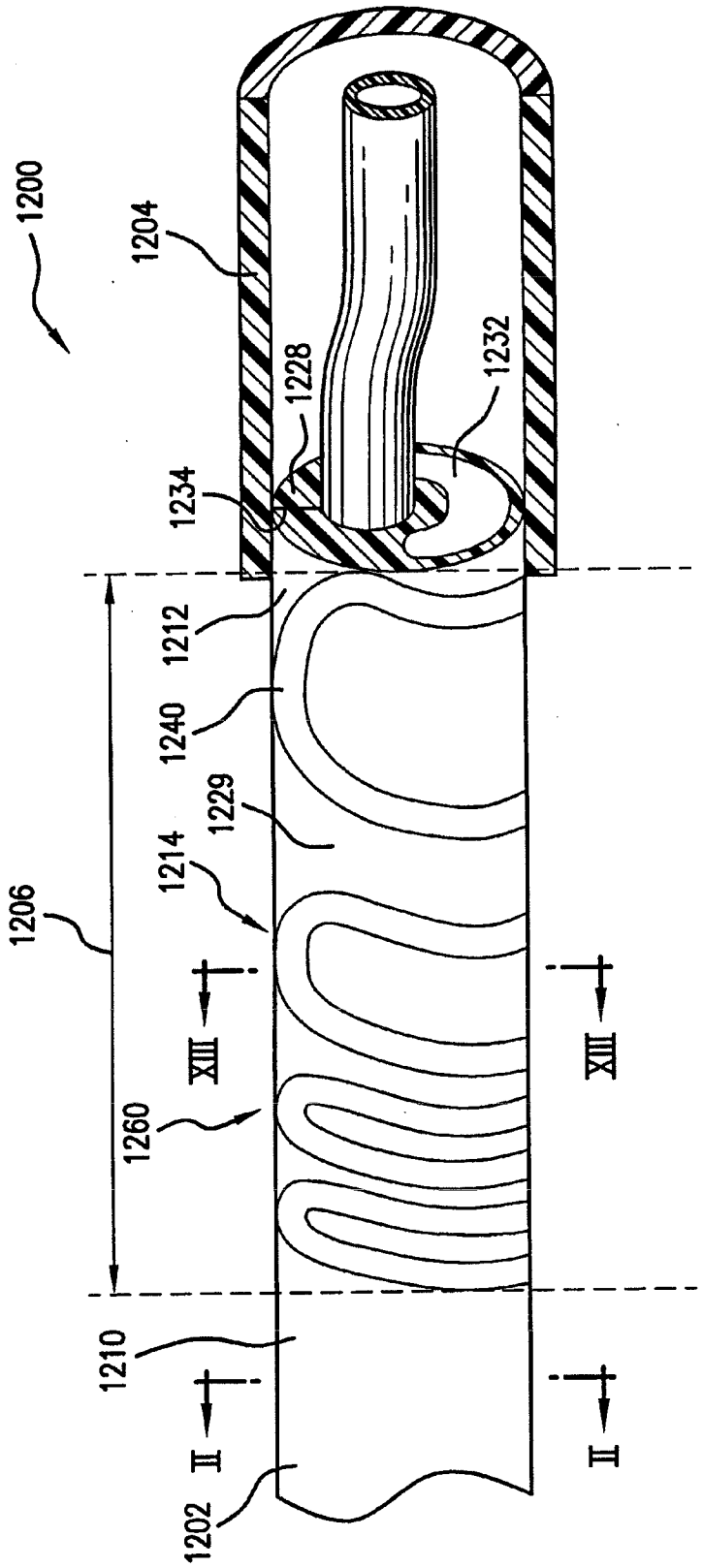
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FIG. 12

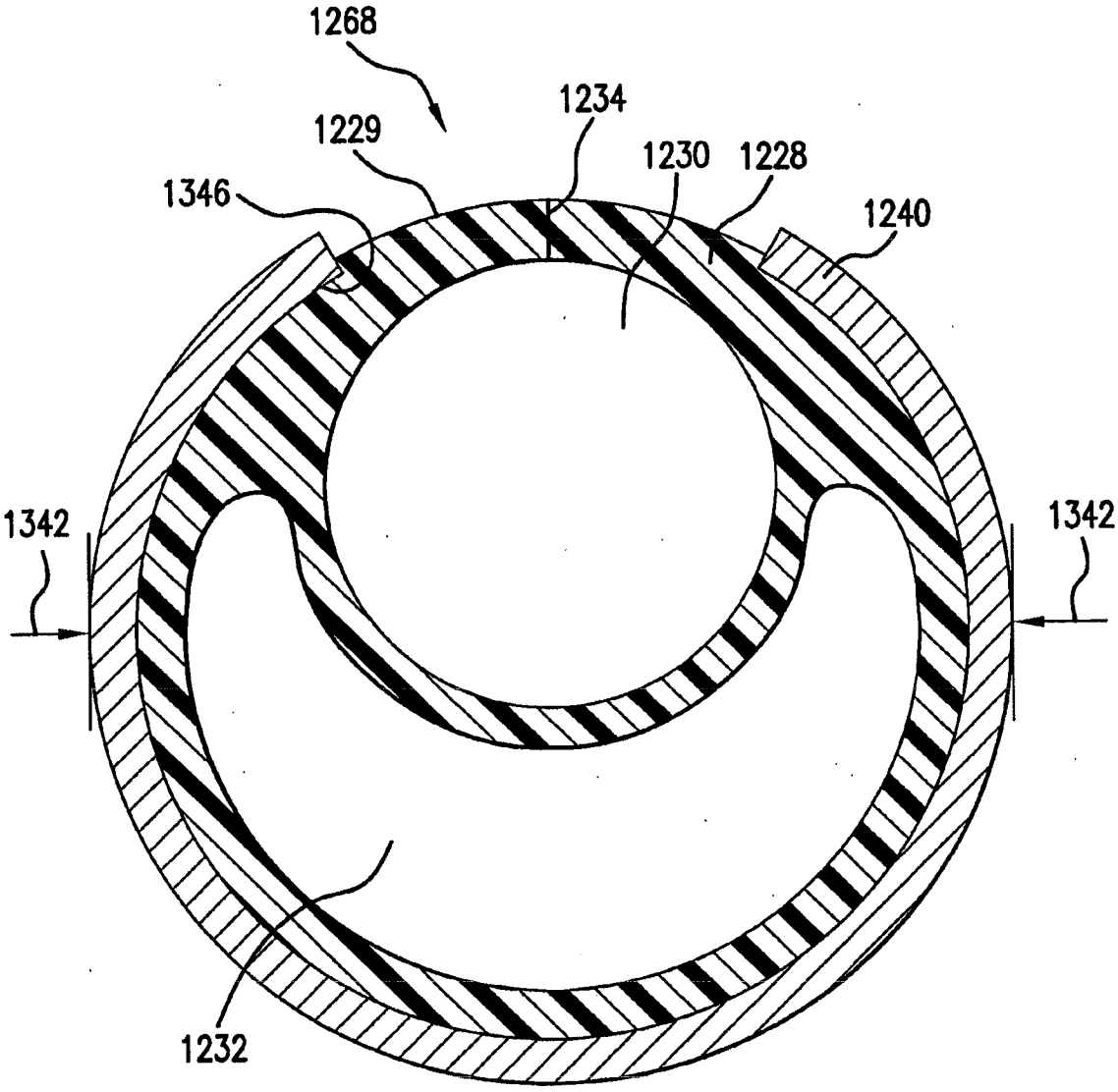

FIG. 13

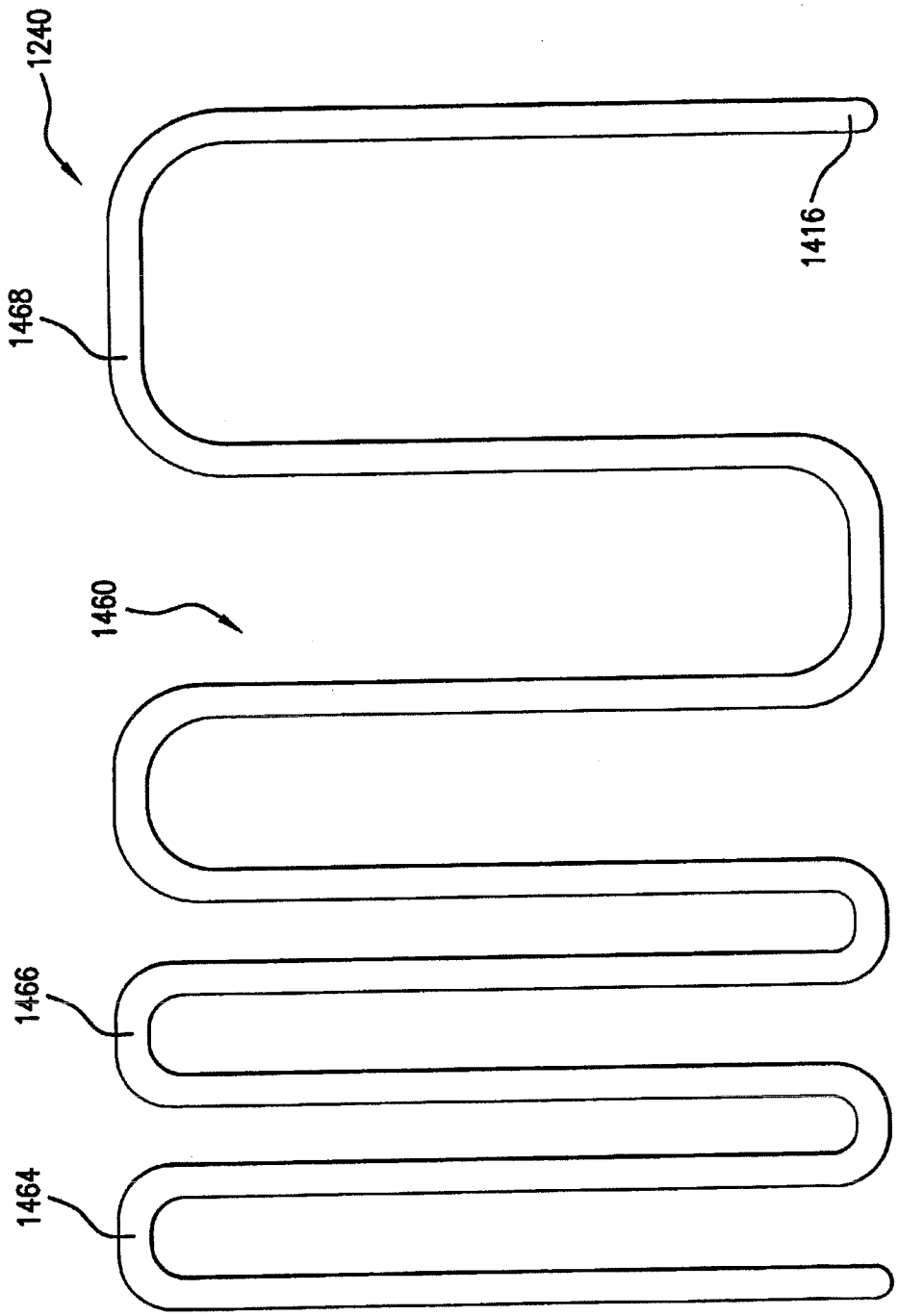

FIG. 14

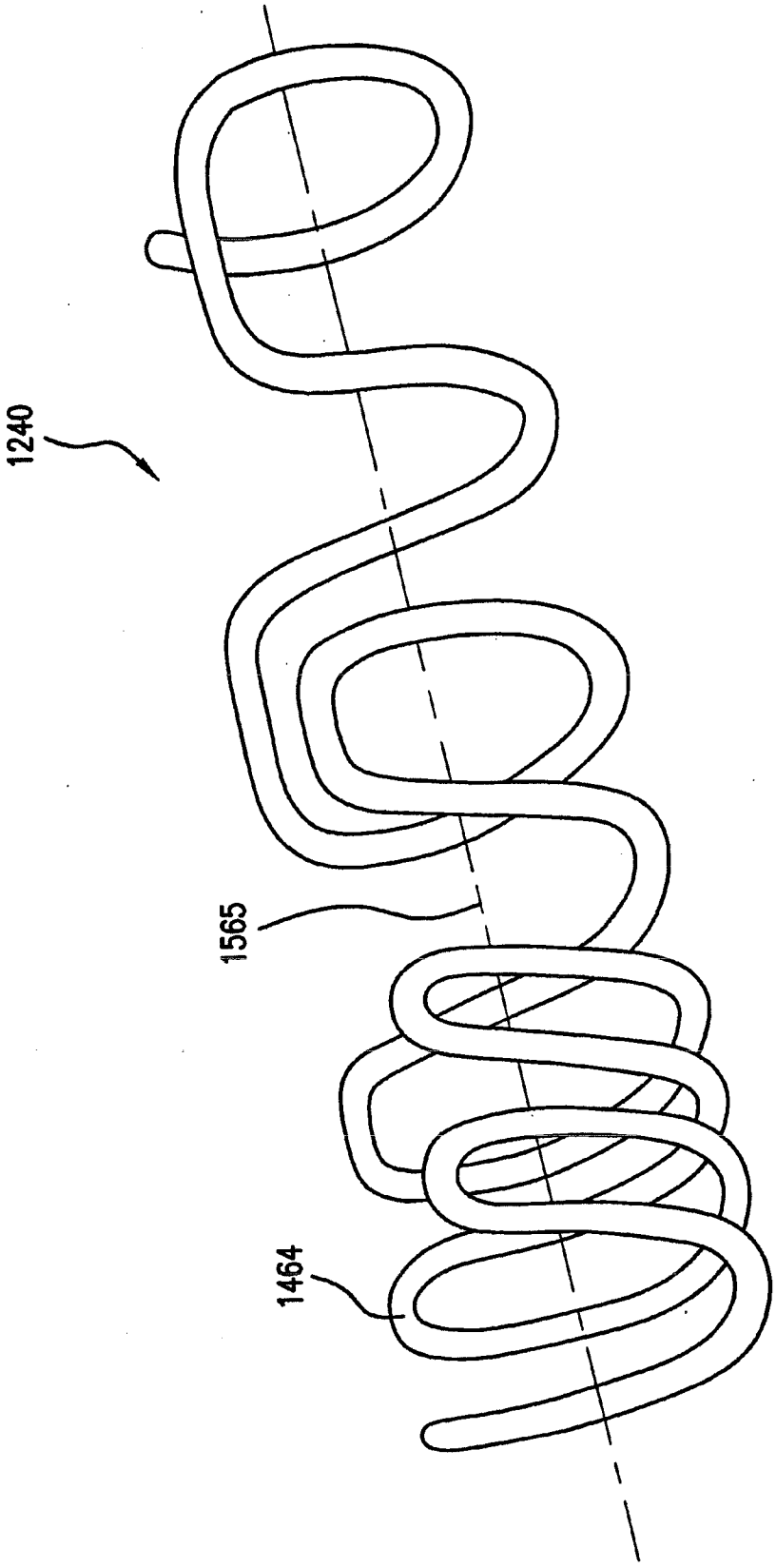

FIG. 15

TRANSITION SECTION FOR A CATHETER

FIELD OF THE INVENTION

[0001] The present invention is directed to a catheter for use in intralumenal procedures within particularly tortuous vessels.

BACKGROUND OF THE INVENTION

[0002] Cardiovascular disease, including atherosclerosis, is the leading cause of death in the U.S. The medical community has developed a number of methods and devices for treating coronary heart disease, some of which are specifically designed to treat the complications resulting from atherosclerosis and other forms of coronary arterial narrowing.

[0003] One method for treating atherosclerosis and other forms of coronary narrowing is percutaneous transluminal coronary angioplasty, commonly referred to as "angioplasty" or "PTCA". The objective in angioplasty is to enlarge the lumen of the affected coronary artery by radial hydraulic expansion. The procedure is accomplished by inflating a balloon of a balloon catheter within the narrowed lumen of the coronary artery.

[0004] In addition to PTCA, catheters are used for delivery of stents or grafts, therapeutic drugs (such as vaso-occlusion agents or tumor treatment drugs) and radiopaque agents for radiographic viewing. Other uses for such catheters are well known in the art.

[0005] The anatomy of coronary arteries varies widely from patient to patient. Often a patient's coronary arteries are irregularly shaped, highly tortuous and very narrow. The tortuous configuration of the arteries may present difficulties to the physician in proper placement of a guidewire, and advancement of a catheter to a treatment site. A highly tortuous coronary anatomy typically will present considerable resistance to advancement of the catheter over the guidewire.

[0006] Therefore, it is important for a catheter to be highly flexible. However, it is also important for a catheter shaft to be stiff enough to push the catheter into the vessel in a controlled manner from a position far away from the distalmost point of the catheter.

[0007] Conventional catheter shafts for PTCA and other procedures typically include a proximal shaft, a transition section and a distal shaft having a flexible distal tip. In particular, the catheters have a proximal shaft, which is generally rigid for increased pushability and a more flexible distal shaft with a flexible distal tip for curving around particularly tortuous vessels. Often the proximal shaft is made stiff by the insertion of a thin biocompatible tube, such as a stainless steel hypotube, into a lumen formed within the proximal shaft. The transition section is the portion of the catheter shaft between the stiffer proximal shaft and the more flexible distal shaft, which provides a transition in flexibility between the two portions.

[0008] With some types of catheter construction, when an increase in resistance occurs during a procedure there is a tendency for portions of the catheter to collapse, buckle axially or kink, particularly in an area where flexibility of the catheter shaft shifts dramatically. Consequently, the transition section is often an area where the flexibility of the catheter gradually transitions between the stiff proximal shaft and the flexible distal shaft. It is known in the art to create a more gradual flexibility transition by spiral cutting a distal end of the hypotubing used to create stiffness in the proximal shaft. Typically, the spiral cut is longitudinally spaced farther apart at the hypotube proximal end creating an area of flexibility, and longitudinally spaced closer together at the hypotube distal end creating an area of even greater flexibility.

[0009] In a typical PTCA procedure, it may be necessary to perform multiple dilatations, for example, using various sized balloons. In order to accomplish the multiple dilatations, the original catheter must be removed and a second catheter tracked to the treatment site. When catheter exchange is desired, it is advantageous to leave the guidewire in place while the first catheter is removed to properly track the second catheter.

[0010] Two types of catheters commonly used in angioplasty procedures are referred to as over-the-wire (OTW) catheters and rapid exchange (RX) catheters. A third type of catheter with preferred features of both OTW and RX catheters, which is sold under the trademarks MULTI-EXCHANGE, ZIPPER MX, ZIPPER, and/or MX, is discussed below. An OTW catheter's guidewire shaft runs the entire length of the catheter and is attached to, or enveloped within, an inflation shaft. Thus, the entire length of an OTW catheter is tracked over a guidewire during a PTCA procedure. A RX catheter, on the other hand, has a guidewire shaft that extends within only the distalmost portion of the catheter. Thus, during a PTCA procedure only the distalmost portion of a RX catheter is tracked over a guidewire.

[0011] If a catheter exchange is required while using a standard OTW catheter, the user must add an extension onto the proximal end of the guidewire to maintain control of the guidewire, slide the catheter off of the extended guidewire, slide the new catheter onto the guidewire and track back into position. Multiple operators are required to hold the extended guidewire in place while the original catheter is changed out.

[0012] A RX catheter avoids the need for multiple operators when changing out the catheter. With a rapid exchange catheter, the guidewire is outside the shaft of the catheter for all but the distalmost portion of the catheter. The guidewire can be held in place without an extension when the catheter is removed from the body. However, one problem associated with RX catheters is that the exposed portion of the guidewire may become tangled with the catheter shaft during use.

[0013] In addition, there are instances when the guidewire and not the catheter must be replaced. An OTW catheter, with the guidewire lumen extending the entire length of the catheter, allows for simple guidewire exchange. With a RX catheter, the guidewire, and most of the catheter, must be removed from the body in order to exchange guidewires. Essentially the procedure must then start anew because both the guidewire and the catheter must be retracked to the treatment site.

[0014] A balloon catheter capable of both fast and simple guidewire and catheter exchange is particularly advantageous. A catheter designed to address this need is sold by

Medtronic AVE, Inc. of Santa Rosa, Calif. under the trademarks MULTI-EXCHANGE, ZIPPER MX, ZIPPER and/or MX (hereinafter referred to as the "MX catheter"). An MX catheter is disclosed in U.S. Pat. No. 4,988,356 to Crittenden et al., and in co-pending U.S. patent application Ser. No. 10/116,234, filed Apr. 4, 2002, both of which are incorporated in their entirety herein by reference.

[0015] The MX catheter includes a catheter shaft having a guidewire lumen positioned side-by-side with an inflation lumen. The MX catheter also includes a longitudinal cut that extends along the catheter shaft and that extends radially from the guidewire lumen to an exterior surface of a catheter shaft. A guide member through which the shaft is slidably coupled cooperates with the longitudinal cut such that a guidewire may extend transversely into or out of the guidewire lumen at any location along the longitudinal cut's length. By moving the shaft with respect to the guide member, the effective over-the-wire length of the MX catheter is adjustable.

[0016] The guidewire is threaded into a guidewire lumen opening at the distal end of the catheter and out through the guide member. The guidewire lumen envelops the guidewire as the catheter is advanced into the patient's vasculature. Furthermore, the indwelling catheter may be removed by withdrawing the catheter from the patient while holding the proximal end of the guidewire and the guide member in a fixed position. When the catheter has been withdrawn to the point where the distal end of the slot has reached the guide member, the distal portion of the catheter over the guidewire is of a sufficiently short length that the catheter may be drawn over the proximal end of the guidewire without releasing control of the guidewire or disturbing its position within the patient.

[0017] When both an inflation lumen and a guidewire lumen are generally circular in shape, a side-by-side lumen configuration generally creates a catheter shaft having an oblong or oval shaped cross-section. However, a catheter with an oblong shaped cross-section may not readily traverse the generally circular shaped body lumens as effectively as a catheter having a generally circular shaped cross-section.

BRIEF SUMMARY OF THE INVENTION

[0018] In light of the foregoing discussed in the background section, the present invention is directed to a catheter shaft with a substantially circular cross-section having a rigid proximal shaft, a flexible distal shaft and a transition section, which gradually increases in flexibility from a proximal to a distal end thereof due to the inclusion of a transition means. The transition section has a proximal end and a distal end, such that the proximal end is in communication with the proximal shaft while the distal end is in communication with the distal shaft.

[0019] At least the proximal shaft defines a guidewire lumen and an inflation lumen. The inflation lumen is generally an arcuate shaped lumen (i.e., has an arcuate shaped cross-section) that cradles the guidewire lumen along the length of the proximal shaft. The proximal shaft also includes a reinforcing means. The reinforcing means provides increased pushability of the proximal shaft for controlling a distal portion of the catheter shaft from a proximal position. The reinforcing means may be an arcuate shaped tube inserted into the inflation lumen. Alternatively, the reinforcing means may be a rod, a long, thin plate or a skived or halved metal or thermoplastic tube inserted into the inflation lumen. Further, the reinforcing means may be entirely embedded in an extruded thickness of the proximal shaft.

[0020] Thus, the transition section is proximally defined where the stiffness of the reinforcement means ends or begins to be reduced and distally defined by the location of a transition means. For example, the transition section may contain a spiral helix as the transition means. The spiral helix may be disposed on the outside of the transition section or inside the transition section. Alternatively, the spiral helix may be bonded to the transition section, or may be positioned to cover more than one of the transition section, proximal shaft or distal shaft. The spiral helix may be partially bonded and partially free-floating. Alternatively, the spiral helix may be entirely free-floating within the transition section and held in place by a "bumped" reduction in the diameter between the transition section and the distal shaft. Also, the spiral helix may be extruded into the tubing of the transition section.

[0021] The transition means may be a continuation of the reinforcing means used in the proximal shaft, wherein the reinforcing means is skived or reduced as it extends distally from the proximal end to the distal end of the transition section. Thus, as the substance of the reinforcing means is reduced, the transition section becomes more flexible along its length.

[0022] If the catheter is an MX catheter, it has a longitudinal cut that is generally found between the guidewire lumen and an exterior surface of the proximal shaft. If the longitudinal cut continues into the transition section, any transition means located in or around the inflation lumen will not affect the distal movement of a guide member along the longitudinal cut. Thus, a skived or reduced reinforcing means within the inflation lumen will not affect this MX feature. However, a spiral helix located in or around the guidewire lumen may affect how far distally a guide member can move along a catheter shaft. Thus, the transition means in an MX catheter may be a U-shaped wire or ribbon sleeve that operates similarly to the spiral helix while providing an opening to access the longitudinal cut along the transition section. The U-shaped wire sleeve can be bent onto an exterior of transition section or it may be embedded into an extruded transition section.

[0023] Further features and advantages of the invention, as well as the structure and operation of various embodiments of the invention, are described in detail below with reference to the accompanying drawings. It is noted that the invention is not limited to the specific embodiments described herein. Such embodiments are presented herein for illustrative purposes only. Additional embodiments will be apparent to persons skilled in the relevant art based on the teachings contained herein.

BRIEF DESCRIPTION OF THE FIGURES

[0024] The accompanying drawings, which are incorporated herein and form a part of the specification, illustrate the present invention and, together with the description, further serve to explain the principles of the invention and to enable a person skilled in the pertinent art to make and use the invention.

[0025] **FIG. 1** is a perspective view in partial cross-section of a catheter shaft according to an embodiment of the present invention.

[0026] **FIG. 2** is a cross-section view of a proximal shaft of the present invention taken along line II-II of **FIGS. 1, 5, 7, 8, 9** and **12**.

[0027] **FIGS. 3A and 3B** are alternative cross-section views of a proximal shaft of the present invention taken along line II-II of **FIGS. 1, 5, 7, 8, 9** and **12**.

[0028] **FIGS. 4A and 4B** are alternative cross-section views of a proximal shaft of the present invention taken along line II-II of **FIGS. 1, 5, 7, 8, 9** and **12**.

[0029] **FIG. 5** is a perspective view of a catheter shaft according to another embodiment of the present invention.

[0030] **FIG. 6** is a cross-section view of a transition section of the present invention taken along line VI-VI of **FIG. 5**.

[0031] **FIG. 7** is a perspective view in partial cross-section of a catheter shaft according to another embodiment of the present invention.

[0032] **FIG. 8** is a perspective view in partial cross-section of a catheter shaft according to another embodiment of the present invention.

[0033] **FIG. 9** is a perspective view in partial cross-section of a catheter shaft according to another embodiment of the present invention.

[0034] **FIG. 10** is a cross-section view of a transition section of the present invention taken along line X-X of **FIG. 9**.

[0035] **FIG. 11** is a cross-section view of a transition section of the present invention taken along line XI-XI of **FIG. 9**.

[0036] **FIG. 12** is a perspective view in cross-section of a catheter shaft according to another embodiment of the present invention.

[0037] **FIG. 13** is a cross-sectional view of a transition section of the present invention taken along a line XIII-XIII of **FIG. 12**.

[0038] **FIG. 14** is a bent ribbon or wire used to form a U-shaped sleeve of the present invention.

[0039] **FIG. 15** is a perspective view of the U-shaped sleeve of the present invention as seen in **FIG. 10**.

DETAILED DESCRIPTION OF THE INVENTION

[0040] The present invention will be described with reference to the accompanying drawings. The drawing in which an element first appears is typically indicated by the leftmost digit(s) in the corresponding reference number.

[0041] **FIG. 1** shows a partial perspective view and partial cross-section of an embodiment of the present invention. In particular, **FIG. 1** shows a catheter shaft **100** that includes a proximal shaft **102**, a distal shaft **104** and a transition section **106**. In this case, transition section **106** has a proximal end **108**, which is defined by a distal end **110** of proximal shaft **102** and fluidly connected thereto. In the embodiment shown in **FIG. 1**, transition section **106** has a distal end **112** which is defined by a transition means **114**, particularly by a distal end **116** of transition means **114**. The distal end **112** of transition section **106** is fluidly connected to a proximal end **118** of distal shaft **104**.

[0042] In the embodiment of **FIG. 1**, distal shaft **104** includes a coaxial guidewire lumen **120** defined by an inner shaft **122**. Distal shaft **104** also includes an outer shaft **124**, shown in **FIG. 1** in partial cross-section. The area between outer shaft **124** and inner shaft **122** defines an inflation lumen **126**. Proximal shaft **102** is made from a single extruded shaft **128** with a proximal guidewire lumen **230** and a proximal inflation lumen **132**.

[0043] Outer shaft **124**, inner shaft **120** and extruded shaft **128** are manufactured separately from thermoplastic materials, particularly high-density polyethylene, polyimide, polyamides, polyolefins and various other polymeric material. Preferably, outer shaft **124**, inner shaft **120** and extruded shaft **128** are made from a polyethylene block amide (PEBA) copolymer. Outer shaft **124**, inner shaft **120** and extruded shaft **128** are bonded together by an adhesive bond, a lap joint thermal compression bond, laser welding or ultrasonic welding or another method of bonding these thermoplastic materials together. Outer shaft **124** and inner shaft **120** may be extruded, molded or formed in another process known in the art for producing tubing used in a medical device.

[0044] **FIG. 1** and **FIG. 2** show a cross-section of one embodiment of proximal shaft **102**. **FIG. 1** shows where proximal shaft **102** meets transition section **106**. **FIG. 2**, however, shows a cross-section of proximal shaft along a line II-II of **FIG. 1**.

[0045] As seen in **FIGS. 1 and 2**, proximal shaft **102** includes extruded shaft **128** having a generally circular exterior surface **129** when viewed in cross-section in **FIG. 2**. Extruded shaft **128** defines a generally circular guidewire lumen **230** by a first interior surface **231**. Extruded shaft **128** also defines arcuate shaped inflation lumen **132** by a second interior surface **133**. The curved shape of inflation lumen **132** cradles guidewire lumen **230**, so that proximal shaft **102** has an overall generally circular shaped cross-section.

[0046] One skilled in the art can appreciate that in an alternate embodiment a guidewire lumen may be arcuate shaped while an inflation lumen is generally circular. However, it is easier to track a guidewire through a circular shaped guidewire lumen rather than an arcuate shaped one. Inflation lumen **132** functions to fluidly communicate an inflation fluid with a balloon (not shown) at its distal end, so it may be of any shape, provided that enough volume of fluid can flow therethrough to inflate the balloon.

[0047] A side-by-side lumen arrangement, such as that shown in **FIGS. 1 and 2**, is particularly suited to an OTW or a MX catheter shaft type. The embodiment of proximal shaft **102** of **FIG. 2** is an MX catheter shaft because it includes a longitudinal cut **134** through which a guidewire can exit guidewire lumen **230**. An OTW catheter shaft is similar to **FIG. 2**, but without longitudinal cut **134**. A catheter shaft **100** with a generally circular cross-section easily traverses a body lumen, which also has a generally circular shaped cross-section. Thus, an OTW or MX catheter having the structure of **FIG. 2** may have a smaller profile

and is easier to navigate through a body lumen than a conventional OTW or MX catheter having an oblong or oval cross-section.

[0048] A RX catheter has a single lumen proximal shaft, because it has a guidewire lumen only at a very distal portion of its catheter shaft **100**. In a RX catheter, the cross-section shown in **FIG. 2** could occur at the very distalmost portion of its proximal shaft or only in a distal or transition section.

[0049] One skilled in the art can appreciate how the transition section and various transition means of the present invention, described in detail below, may be suitable for a fixed wire, OTW, RX or MX catheter type.

[0050] In an embodiment of the present invention, proximal shaft **102** is reinforced with a reinforcing means. A reinforcing means provides proximal shaft **102** with increased pushability. In other words, the reinforcing means makes the proximal shaft **102** stiffer, so that a user can control the catheter while it traverses the tortuous pathways of the body lumen from a proximal position. In one embodiment, a reinforcing means is used along an entire length of the proximal shaft **102**.

[0051] In conventional catheters, reinforcing means may be a thin metal tube, such as a stainless steel hypotube, inserted into a guidewire lumen or inflation lumen in order to reinforce the proximal shaft. An MX catheter design, however, is not suitable for having a hypotube inserted within guidewire lumen **230** because the guidewire must be able to escape out of longitudinal cut **134** made between the guidewire lumen and exterior surface **129** of extruded shaft **128** as shown in **FIG. 2**. Meanwhile, a hypotube is not suitable for use in the inflation lumen shown in **FIG. 2** because the inflation lumen is arcuate shaped rather than circular. Thus, an embodiment of the present invention must have a different type of reinforcing means.

[0052] **FIG. 2** shows an arcuate shaped reinforcing means **135**. Arcuate shaped reinforcing means **135** may be a tubing that is cast in the particular arcuate shape or it may be a thin tube, such as a hypotube, which has been crimped to form the arcuate shape. Alternatively, reinforcing means **135** may be a plastic material having a high rigidity.

[0053] **FIG. 3A** and **FIG. 3B** show further embodiments of a reinforcing means. Reinforcing means **335A** and **335B** may be a metal or thermoplastic plate or rod in a flat, curved or cylindrical shape. If the reinforcing means **335A** or **335B** are curved, they may be pressed into shape, cut from a hypotube, or extruded into a curved shape. The advantage of having a reinforcing means other than a hypotube is that a rod or plate, such as that shown in **FIG. 3A**, takes up less room inside inflation lumen **132**, thereby allowing for a greater volume of inflation fluid to pass therethrough. Further, without the double walls of a tubular reinforcing means, the overall dimensions of catheter shaft **100** may be reduced, such that the catheter shaft will then have a lower profile. The type of reinforcing means shown in **FIG. 3A** could also be inserted into the guidewire lumen of a generally circular catheter shaft **100**, provided that it does not interfere with a guidewire's movement through a guidewire lumen or its exit through longitudinal cut **134** of an MX catheter type.

[0054] **FIG. 3B** shows a slightly different arcuate shaped inflation lumen **132** including a hypotube reinforcing means **335B**, in which a top portion has been skived off of the hypotube. Various other shapes of inflation lumen **132** similarly reinforced would be appropriate for use in this invention.

[0055] In another embodiment, seen in **FIG. 4A** and **FIG. 4B**, a reinforcing means **435** may be embedded into the extruded shaft **128**. In **FIG. 4A**, reinforcing means **435** is a half tube, such as half of a stainless steel hypotube, which has been extruded into a portion **437** of extruded shaft **128** on the opposite side of inflation lumen **132** from guidewire lumen **230**. Alternatively, a reinforcing means may be extruded into another portion of extruded shaft **128**. For example, reinforcing means may be located at portion **439** between guidewire lumen **230** and inflation lumen **132**. Also, as shown in **FIG. 4B**, support strips **436A** and **436B** may be placed in another location **438A** and **438B** just adjacent to guidewire lumen **230**. Support strips **436A** and **436B** may be extruded along with reinforcing means **435**, or as an alternative thereto. Further, only one or the other of support strips **436A** and **436B** may be embedded into extruded shaft **128**. Other catheter designs such as the coaxial OTW, fixed wire and RX catheters may also have a reinforcing means extruded into the extruded shaft **128** of the proximal shaft **102**.

[0056] **FIGS. 2, 3A, 3B, 4A** and **4B** provided only a few ways in which proximal shaft may be reinforced in accordance with the present invention. The present invention may be suitable for use with other reinforcing techniques.

[0057] In **FIG. 1**, the coaxial structure of distal shaft **104** extends into transition section **106**, such that extruded shaft **128** is inserted and bonded inside outer shaft **124**. Similarly, inner shaft **122** is inserted into and bonded to proximal guidewire lumen **230** of proximal shaft **102**. In an alternate embodiment, however, extruded shaft **128** of proximal shaft **102** may extend distally into transition section **106** without the additional support provided by reinforcing means **135**. For example, **FIG. 9** shows such a transition section, as will be discussed in detail below.

[0058] As seen in to **FIG. 1**, distal end **110** of proximal shaft **102** occurs simultaneously with a distal end **138** of reinforcing means **135**. The distalmost end of catheter shaft **100** must be highly flexible to curve around the most tortuous parts of the vasculature. However, an abrupt end to the stiffness created by reinforcing means 135, of **FIG. 1**, may cause a procedurally disastrous kink in catheter shaft **100**. Thus, transition section **106** extends from distal end **138** of reinforcing means **135** to distal end **116** of transition means **114** to provide a transition between the rigidity of proximal shaft **102** and the flexibility of distal shaft **104**.

[0059] In a conventional catheter shaft, a transition means may be created by spiral cutting the reinforcing means. However, since the reinforcing means in this case is not a circular hypotube, the present invention provides transition means alternative to spiral cutting a reinforcing means.

[0060] In **FIG. 1**, transition means **114** is a spiral helix **140**. Spiral helix **140** may be made of a metal wire or ribbon twisted to form a coil. Alternatively, the spiral helix **140** may be made from a thermoplastic polymer having sufficient strength to provide support to transition section **106**. Preferably, spiral helix **140** is a wire ribbon, which will lay flat, such that it may be embedded into outer shaft **124** upon

extrusion thereof without significantly increasing the outer diameter of outer shaft **124**. Having spiral helix **140** embedded into an extruded outer shaft **124** allows for easier assembly of catheter shaft **100** due to fewer individual components. In addition, it retains a smooth outer wall surface to aid in moving through a body lumen.

[0061] Spiral helix **140** provides a gradual increase in flexibility by having the pitch of the coils closer together at proximal end **108** and further apart at distal end **116** of transition section **106**. Further, moving distally along spiral helix **140** the windings become farther apart. Where the windings of the coil are closer together, the spiral helix **140** has less movement, thus making the transition section **106** stiffer. However, where the coils are farther apart, the spiral helix **140** has more movement and more flexibility. Therefore, the spiral helix **140** provides a gradual transition in flexibility along transition section **106**. In addition, spiral helix **140** may be of any length and the pitch may be altered such that a desired flexibility occurs at a particular location along transition section **106**.

[0062] In an alternate embodiment, extruded shaft **128** may extend into transition section **106** without reinforcing means **135**. Thus, transition means **114** may be disposed in outer surface **124** in a location where extruded shaft **128** and outer shaft **124** overlap. Alternatively, spiral helix **140** may be extruded into extruded shaft **128** at a position distal to the distal end **138** of reinforcing means **135**.

[0063] **FIG. 5** shows an exterior perspective view of an alternate embodiment of the present invention. **FIG. 5** includes a proximal shaft **102**, a distal shaft **104** and a transition section **106**, as discussed above for **FIG. 1**. For example, proximal shaft **102** may have a cross-section along line II-II, which takes the form of any of the cross-sections shown in **FIGS. 2-4** or may include another type of reinforcing means.

[0064] However, **FIG. 5** has a spiral helix **540** as transition means **114** positioned on an outer surface **544** of outer shaft **124** rather than embedded therein. Again, spiral helix **540** may be a coiled ribbon or wire, but is preferably a ribbon, which lays flat against the outer surface **544** of outer shaft **124**.

[0065] **FIG. 6** shows a cross-sectional view of transition section **106** at a line VI-VI of **FIG. 5**. **FIG. 6** shows transition section **106** having inner shaft **122** defining guidewire lumen **120**. Transition section **106** also has inflation lumen **126** defined by the area between inner shaft **122** and outer shaft **124**. **FIG. 6** shows how a ribbon spiral helix **540** creates a small outer diameter **642**, by remaining somewhat flush to outer surface **544**. A wire spiral helix **540** would have a round cross-section rather than the generally rectangular cross-section shown in **FIG. 6**. **FIG. 6** also shows how outer surface **544** of outer shaft **124** may have an indentation **646**, which receives spiral helix **540** to create an even smaller outer diameter **642**. A laser may accurately draw indentation **646** onto outer surface **544** or indention **646** may be imprinted onto a soft polymer surface. Spiral helix **540** may be secured to the outer surface **544** along the entire length of spiral helix **540** by adhesive bonding, heat fusion, laser bonding, an interference fit or another type of bonding.

[0066] Alternatively, spiral helix **540** may be fully or partially free-floating along outer surface **544** of outer shaft **124**. As such only a portion or an end of spiral helix **540** would be bonded to outer surface **544** of outer shaft **124**. A fully or partially free-floating spiral helix **540** may provide greater flexibility for transition section **106**, but may cause greater friction against the walls of a body lumen when inserted therein. Alternatively, spiral helix **540** may be placed between outer surface **544** and a thin coating or covering, such as a layer of polyolefin, polyimide or polyamide, to reduce friction when moving through a body lumen and to hold spiral helix **540** in place.

[0067] Spiral helix **540** may vary in pitch (i.e. distance between adjacent windings) from a proximal end **548** to a distal end **516**. In particular, near the proximal end **548**, spiral helix **540** has a tight pitch, wherein the windings are close together. At the distal end **516**, spiral helix **540** has a looser pitch, wherein the windings are farther apart. Thus, from proximal end **548** to distal end **516**, the flexibility of spiral helix **540** increases with an increase in the pitch of the coils, providing transition section **106** with a gradual increase in flexibility.

[0068] **FIG. 7** shows another embodiment of the present invention. **FIG. 7** shows a catheter shaft **700** similar to catheter shaft **100** of **FIG. 1**, with a proximal shaft **702**, distal shaft **704** and transition section **706**. Proximal shaft **702** may have a cross-section along line II-II, which takes the form of any of the cross-sections shown in **FIGS. 2-4** or may include another type of reinforcing means. In the embodiment of **FIG. 7**, transition means **714** is a spiral helix **740** positioned between outer shaft **724** and inner shaft **722**. In other words, spiral helix **740** is located within inflation lumen **726**.

[0069] Spiral helix **740** may be bonded at a proximal end **748** to proximal shaft **702**. If so, a distal end **716** of spiral helix **740** may be free-floating inside outer shaft **724**. Alternatively, spiral helix **740** may be bonded to an interior surface **750** of outer shaft **724** at one or more locations or along the entire length of spiral helix **740**. For example, the distal end **716** of the spiral helix **740** may be bonded to the outer shaft **724**, and the proximal end **748** may be free-floating. Spiral helix **740** also may be located between outer shaft **724** and a coating or covering used to keep spiral helix **740** in position and to isolate spiral helix **740** from the inflation fluid flow. In yet another embodiment, a spiral helix may be used that has smaller outer diameter than the spiral helix **740** shown in **FIG. 7**, such that it lays flat against an outer surface **752** of inner shaft **722**, in a similar fashion to spiral helix **540** which lies against outer shaft **124** as shown in **FIGS. 5 and 6**.

[0070] As discussed above, from proximal end **748** to distal end **716**, the flexibility of spiral helix **740** increases with an increase in the pitch between the windings, providing transition section **706** with a gradual increase in flexibility.

[0071] Again, a spiral helix that is free floating will provide the greatest flexibility. However, spiral helix **740** of **FIG. 7**, if not bonded to any part of proximal shaft **702** or transition section **706**, may move proximally or distally within outer shaft **724**. **FIG. 8**, however, shows another embodiment of the present invention, identical to **FIG. 7**, except that outer shaft **824** has a "bumped" region **854** wherein the diameter of outer shaft **824** reduces from a first diameter **856** to a second diameter **858**. The second diameter

858 is less than the diameter of the spiral helix 840, thus preventing spiral helix 840 from shifting proximally and distally inside of outer shaft 824. In the catheter shaft 800 of FIG. 8, spiral helix 840 can float freely for maximum flexibility.

[0072] If a catheter shaft of the previously described embodiments, such as catheter shaft 100 as shown in FIG. 1, is utilized in a MX catheter design, then the longitudinal cut 134 in the proximal shaft 102 will only be accessible up to the spiral helix 140, because the spiral helix forms a closed loop around either the interior or the exterior of the transition section 106. Thus, a guide member of an MX catheter will not be able to open longitudinal cut 134 at a location of or distal to the spiral helix 140. This is true for the spiral helix of each of the previously described embodiments.

[0073] With reference to FIG. 1, the guide member (not shown) of an MX catheter opens longitudinal cut 134 and leads the guidewire out of guidewire lumen 230. However, in order that catheter shaft 100 is easily exchanged, the guide member must move distally far enough along the catheter shaft 100 that the operator can reach the guidewire distally of catheter shaft 100 while holding a proximal portion of the guidewire. Thus, distal end 110 of proximal shaft 102 (i.e., where longitudinal cut 134 ends) must be sufficiently close to the distal end of catheter shaft 100 for the MX catheter function to operate. However, a closed loop spiral helix as a transition means, as described in each of the previous embodiments, is well suited for use at any location with OTW, fixed wire and most RX catheters.

[0074] FIG. 9 shows another embodiment of the present invention. Catheter shaft 900 of FIG. 9 also includes a proximal shaft 902, a distal shaft 904 and a transition section 906. Also proximal shaft 902 may have a cross-section along line II-II that takes the form of any of the cross-sections shown in FIGS. 2-4 or may include another type of reinforcing means. In this case, extruded shaft 928 extends into transition section 906. In this embodiment, a transition means 914 is essentially a portion 940 of a reinforcing means 935 in which part of the structure of the reinforcing means is gradually removed along the length of transition section 906. For example, in FIG. 9, a proximal portion of reinforcing means 935 is an arcuate shaped tube, such as is shown in FIG. 2. However, distally of the distal end 910 of proximal shaft 902 the reinforcing means 935 becomes reduced in size or shape to be thinner and more flexible. In this case, reinforcing means 935 may be skived away to almost nothing at a distal end 912 of transition section 906. As the reinforcing means 935 is reduced, the stiffness it provided to the proximal shaft 902 is reduced. Thus, the transition section 906 gradually becomes more flexible.

[0075] The shape and thickness of reinforcing means 935 may be changed in a variety of ways along the reduced portion 940 of reinforcing means 935 in order to achieve the desired flexibility at any location along the length of transition section 906. For example, if reinforcing means 935 is a rod or a metal plate, the rod or metal plate may be made thinner and more flexible at a distal end than at the proximal end where it is used as a reinforcing means.

[0076] Alternatively, the properties of reinforcing means 935 may be altered in portion 940, without changing the physical dimensions of the reinforcing means 935. For example, reinforcing means 935 may be made from a thermoplastic polymer having a particular stiffness in proximal shaft 902. However, in transition section 906 the properties of that polymer can be chemically altered to provide a gradual increase in flexibility along transition section 906. For example, transition section 906 may comprise two materials having different stiffness compositions, such that the concentration of each material (i.e., the percent composition) changes along the length of transition section 906 to provided different characteristics. Further, chemical processing, such as cross-linking, may also change the properties along transition section 906.

[0077] FIGS. 10 and 11 are cross-section views of transition section 906 taken along lines X-X and XI-XI, respectively. FIGS. 10 and 11 show a gradual reduction in the portion 940 of reinforcing means 935, which is shown in phantom in FIG. 9.

[0078] The embodiment of FIG. 9 shows that a longitudinal cut 934 may be used to access a guidewire in guidewire lumen 930 along the length of both the proximal shaft 902 and the transition section 906, at least up to where outer shaft 924 overlaps extruded shaft 928. Thus, a guide member (not shown) may be slid distally along longitudinal cut 934 of proximal shaft 902 until the guide member essentially reaches distal shaft 924. With such a manipulation, the guide wire effectively reduces a distal portion of guidewire lumen 930 so that the guidewire is accessible proximally at the guide member and distally at a distal tip of catheter 900 thereby allowing a single operator catheter exchange. A flat or curved reinforcing member placed anywhere in inflation lumen 932, guidewire lumen 930 or within extruded shaft 928, with the exception of certain locations near longitudinal cut 934, would provide access for a guide member to longitudinal cut 934.

[0079] FIG. 12 shows yet another embodiment of the present invention. In this embodiment, catheter shaft 1200 includes a proximal shaft 1202, a distal shaft 1204 and a transition section 1206. In this case, extruded shaft 1228 extends into transition section 1206, similar to that of FIG. 9. However, reinforcing means 1235 does not extend distally beyond the distal end 1210 of proximal shaft 1202. Thus, guidewire lumen 1230, inflation lumen 1232 and/or extruded shaft 1228 do not have any reinforcing means therein within transition section 1206. In FIG. 12, transition means 1214 is a U-shaped sleeve 1240. U-shaped sleeve 1240 in FIG. 12 is located on the exterior surface 1229 of extruded shaft 1228. U-shaped sleeve has the advantages of the spiral helix described above but does not wrap the entire way around catheter shaft 1200. Thus, the U-shaped sleeve 1240 provides an opening 1260, such that longitudinal cut 1234 may be opened by a guide member up to a position near the distal end 1212 of transition section 1206.

[0080] U-shaped sleeve 1240 may be bonded to the outer surface 1229 of extruded shaft 1228 at any location or along the entire length of U-shaped sleeve 1240 by adhesive bonding, heat bonding, laser bonding or another type of bonding. Similarly to that of a spiral helix, a free-floating U-shaped sleeve 1240 may provide greater flexibility for transition section 1206, but will likely cause greater friction against the walls of a body lumen when inserted therein. U-shaped sleeve 1240 may be place between outer surface 1229 and a thin coating or covering, such as a layer of

polyolefin or polyimide, to reduce friction when moving through a body lumen and to hold U-shaped sleeve **1240** in place. Alternatively, U-shaped sleeve **1240** may be extruded into extruded shaft **1228**.

[**0081**] **FIG. 13** shows a cross-sectional view of transition section **1206** at a line XIII-XIII of **FIG. 12**. **FIG. 13** shows extruded shaft **1228** defining guidewire lumen **1230** and inflation lumen **1232**. **FIG. 13** shows how a U-shaped sleeve **1240** creates a small outer diameter **1342**, by remaining somewhat flush to an outer surface **1229**. **FIG. 13** also shows how outer surface **1229** of extruded shaft **1228** may have an indentation **1346**, which receives U-shaped sleeve **1240** to create an even smaller outer diameter **1342**. **FIG. 13** also shows opening **1268** in U-shaped member **1240**, through which a guide member may travel to open longitudinal cut **1234** and release a guidewire placed within guidewire lumen **1230**.

[**0082**] U-shaped sleeve **1240** may be formed from a ribbon or a wire. Alternatively, U-shaped sleeve **1240** may be made from a thermoplastic polymer having sufficient strength to provide support to transition section **1206**. Preferably, U-shaped sleeve **1240** is a wire ribbon. As shown in **FIG. 13**, a ribbon, having a flatter cross-section than a rounded cross-section of a wire, may provide a lower outer diameter **1342** for catheter shaft **1200**.

[**0083**] **FIG. 14** shows how a ribbon or wire **1460** may be bent into a repeating series of loops **1464** having a generally sinusoidal or zigzag shape. The loops **1464** may be shaped as shown in **FIG. 14**, where the pitch between loops **1464** and the size of loops **1464** increases as you move along the ribbon **1460**. Smaller loop **1466** will not provide transition section **1206** as much flexibility as will larger loop **1468**. Thus, larger loop **1468** is closer to a distal end **1416** of U-shaped sleeve **1240**, where greater flexibility is required. The ribbon **1460** of **FIG. 14** may be formed by bending a ribbon or wire on a form tool. Alternatively, the ribbon or wire **1460** may be stamped out of a metal or plastic sheet.

[**0084**] **FIG. 15** shows how the ribbon or wire **1460** of **FIG. 14** is bent to form U-shaped sleeve **1240**. U-shaped sleeve **1240** generally curves around an axis **1565**, which is a center point of the generally circular catheter shaft **1200**. Loops **1464** are bent up such that opposite ends of loops in **FIG. 14** face the same direction or face each other in **FIG. 15**, depending upon how far U-shaped sleeve is curved. U-shaped sleeve **1240** may be slid onto catheter shaft **1200** and crimped onto outer surface **1229** of extruded shaft **1228** of transition section **1206**, as seen in **FIG. 13**. Alternatively, U-shaped sleeve **1240** may be bent onto extruded shaft **1228** directly from the ribbon or wire shape **1460** of **FIG. 14**.

[**0085**] While the invention has been particularly shown and described with reference to preferred embodiments thereof, it will be understood by those skilled in the art that they have been presented by way of example only, and not limitation, and various changes in form and details can be made therein without departing from the spirit and scope of the invention.

[**0086**] Thus, the breadth and scope of the present invention should not be limited by any of the above-described exemplary embodiments, but should be defined only in accordance with the following claims and their equivalents. Additionally, all references cited herein, including issued U.S. patents, or any other references, are each entirely incorporated by reference herein, including all data, tables, figures, and text presented in the cited references.

[**0087**] The foregoing description of the specific embodiments will so fully reveal the general nature of the invention that others can, by applying knowledge within the skill of the art (including the contents of the references cited herein), readily modify and/or adapt for various applications such specific embodiments, without undue experimentation, without departing from the general concept of the present invention. Therefore, such adaptations and modifications are intended to be within the meaning and range of equivalents of the disclosed embodiments, based on the teaching and guidance presented herein. It is to be understood that the phraseology or terminology herein is for the purpose of description and not of limitation, such that the terminology or phraseology of the present specification is to be interpreted by the skilled artisan in light of the teachings and guidance presented herein, in combination with the knowledge of one of ordinary skill in the art.

What is claimed is:

1. A catheter, comprising:

a proximal shaft defining a guidewire lumen and an inflation lumen, wherein said inflation lumen is arcuate shaped and reinforced with a tube having an arcuate shaped cross-section;

a distal shaft wherein said distal shaft has a greater flexibility than said proximal shaft; and

a transition section having a proximal end and a distal end, said proximal end communicating with said proximal shaft and said distal end communicating with said distal shaft, wherein said transition section has a gradually increased flexibility from said proximal to said distal ends.

2. The catheter of claim 1, wherein said gradually increased flexibility is created by a spiral helix in the transition section.

3. The catheter of claim 2, wherein said spiral helix is positioned on an exterior surface of said transition section.

4. The catheter of claim 2, wherein said spiral helix is positioned against an interior surface of said transition section.

5. The catheter of claim 2, wherein said spiral helix is entirely embedded into an extruded thickness of said transition section.

6. The catheter of claim 2, wherein subsequent windings of said spiral helix are closer together at said proximal end of said transition section and farther apart at said distal end of said transition section.

7. The catheter of claim 2, wherein said spiral helix is made from one of a metal ribbon or metal wire.

8. The catheter of claim 2, wherein said spiral helix is made from a thermoplastic polymer.

9. The catheter of claim 1, wherein said tube includes a skived portion at its distal end that extends within said transition section to achieve said gradually increased flexibility.

10. The catheter of claim 1, wherein said proximal shaft has a longitudinal cut along its length, said longitudinal cut extending in a radial direction between an exterior surface of said proximal shaft and said guidewire lumen.

11. The catheter of claim 10, wherein said longitudinal cut extends distally into said transition section.

12. The catheter of claim 11, wherein said gradually increased flexibility is created by a U-shaped wire sleeve, said wire sleeve having an opening for generally aligning with said longitudinal cut.

13. The catheter of claim 12, wherein said sleeve is a wire formed into a zigzag shape and bent into a generally curved shape.

14. The catheter of claim 13, wherein said sleeve is positioned around an exterior surface of said transition section.

15. The catheter of claim 13, wherein said sleeve is embedded within an extruded thickness of said transition section.

16. The catheter of claim 1, wherein said tube is made from one of a metal and a thermoplastic polymer.

17. A catheter, comprising:

a proximal shaft defining a guidewire lumen and an inflation lumen, wherein said inflation lumen is arcuate shaped and reinforced with a reinforcing means;

a distal shaft wherein said distal shaft has a greater flexibility than said proximal shaft; and

a transition section having a proximal end and a distal end, said proximal end communicating with said proximal shaft and said distal end communicating with said distal shaft, wherein said transition section includes a transition means embedded entirely within an extruded thickness of said transition section.

18. The catheter of claim 17, wherein said reinforcing means is a metal tube having an arcuate cross-section.

19. The catheter of claim 17, wherein said reinforcing means is one of a metal rod, a long thin metal plate, a skived metal tube and a halved metal tube.

20. The catheter of claim 17, wherein said reinforcing means is entirely embedded within an extruded thickness of said proximal shaft.

21. The catheter of claim 17, wherein said reinforcing means is disposed within an interior surface of said proximal shaft defining said inflation lumen.

22. The catheter of claim 17, wherein said transition means is a spiral helix.

23. The catheter of claim 22, wherein said spiral helix has a tight pitch at a first end and a loose pitch at a second end.

24. The catheter of claim 17, wherein said transition means is a portion of said reinforcing means.

25. The catheter of claim 24, wherein said transition means is a skived portion of a tube.

26. The catheter of claim 24, wherein said transition means is a rod that becomes thinner and more flexible along a longitudinal length.

27. The catheter of claim 24, wherein said transition means is a metal plate that become thinner and more flexible along a longitudinal length.

28. The catheter of claim 17, wherein said transition means is a U-shaped wire sleeve.

29. The catheter of claim 28, wherein said U-shaped wire sleeve has a tight pitch at a first end and a loose pitch at a second end.

30. The catheter of claim 17, wherein said transition section is an extension of said distal shaft, such that said transition section is defined by the length of said transition means.

31. The catheter of claim 17, wherein said transition section is an extension of said proximal shaft after a point where said reinforcing means terminates, such that said transition section is defined from a point where said reinforcing means terminates to where said distal shaft begins.

32. The catheter of claim 17, wherein said proximal shaft further includes a longitudinal cut along the length thereof to facilitate the removal of a guidewire from said guidewire lumen.

33. The catheter of claim 32, wherein said longitudinal cut extends distally into said transition section.

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